UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS SAN ANTONIO DIVISION

WAVE NEUROSCIENCE, INC. a Delaware Corporation,

Plaintiff.

VS.

BRAIN FREQUENCY LLC, a Texas Limited Liability Company

Defendant.

Case No. 5:23-CV-00626-XR

Honorable: Xavier Rodriguez

DECLARATION OF MAROM BIKSON IN SUPPORT OF PLAINTIFF'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

1. I have been asked by Plaintiff Wave Neuroscience, Inc. to provide this declaration concerning the meaning of certain claim terms in certain patents at issue in the above-captioned consolidated case. Specifically, I have been asked to provide my opinions on how a person of ordinary skill in the art ("POSITA") would have understood the use of the various claim terms as used in the claims of U.S. Patent Nos. 10,029,111 ("the '111 Patent"), 8,926,490 ("the '490 Patent"), 8,870,737 ("the '737 Patent"), and 8,465,408 ("the '408 Patent") (collectively, "Asserted Patents") that are being asserted against the Defendant in this case. In addition, I have been asked to provide my opinions as to the merits of the proposed claim construction presented by Defendant in Defendant's Opening Claim Construction Brief and the Declaration of Dr. Jared Dempsey, dated May 17, 2024, in support of Defendant's Opening Claim Construction Brief ("Dempsey Declaration").

I. PROFESSIONAL BACKGROUND AND QUALIFICATIONS

2. I am a Professor at the City University of New York in the Department of Biomedical Engineering. I currently teach graduate and undergraduate level biomedical engineering courses, including on biomedical instrumentation. I have previously taught or presented guest lectures at many other universities on neurological stimulation.

- 3. I earned my undergraduate degree in biomedical engineering from Johns Hopkins University in 1995. I received a Ph.D. in biomedical engineering from Case Western Reserve University in 2000.
- 4. I have been involved in biomedical research since 1995. I have been teaching graduate level courses in biomedical engineering since 2003. My research includes numerous past and current projects researching neuromodulation and nerve stimulation. Beginning in 2005, I was involved in grant-funded research on the effect of application of electrical fields on the brain.
- 5. In addition to teaching and research, I am an elected member of the American Institute for Medical and Biological Engineering. I have also served as an editor for a number of scientific journals and texts including Brain Stimulation. I am also on the Board of Directors for the North American Neuromodulation Society.
- 6. I have also authored or co-authored nearly 500 articles, texts, and chapters in my field of expertise, including dozens of publications specifically directed to transcranial electrical and magnetic stimulation (tES and TMS).
- 7. My background and qualifications are more fully set forth in my curriculum vitae, attached as Exhibit 1.

II. STATEMENT OF COMPENSATION

8. I am being compensated for the time I spend on this matter at my usual and customary consulting rate of \$600 per hour. This compensation is not contingent in any way on the outcome of this case or the testimony I provide.

III. MATERIALS CONSIDERED

- 9. In addition to relying on my knowledge and experience in the field of EEG, tES, TMS and neuromodulation, I also considered or relied upon the list of documents attached as Exhibit 2 in preparing this Declaration and forming my opinions contained herein.
- 10. In particular, I have reviewed and considered the Asserted Patents, their respective prosecution histories, Defendant's Opening Claim Construction Brief and the

Dempsey Declaration, and the other documents cited in this declaration in providing my opinions stated herein.

IV. PERSON OF ORDINARY SKILL IN THE ART

- 11. While this issue is not addressed, except in the context of the definiteness requirement in Paragraph 13 of the Dempsey Declaration, it is my understanding that at the claim construction stage of a case, the claims are interpreted from the perspective of a POSITA as of the priority dates of the Asserted Patents.
- 12. Dr. Dempsey fails, in the Dempsey Declaration, to provide any opinion as to the issue of the relevant priority date for any of the Asserted Patents. Accordingly, I assume, as correct, the following priority dates that I have been provided: (1) the priority date of the '111 Patent is April 6, 2012, (2) the priority date of the '490 Patent is September 24, 2008, (3) the priority date of the '737 Patent is September 24, 2008, and (4) the priority date of the '408 Patent is August 6, 2009.
- 13. In his declaration, Dr. Dempsey identifies a Person of Ordinary Skill In The Art as having "a graduate degree in mental health, neuroscience, or a related field with substantially similar courses, and 3-4 years of work experience, in addition to having advanced training and experience in use of either EEG or TMS technology." [Dempsey Decl. ¶ 16]. Given the nature of the technology that is the subject of the Asserted Patents, I disagree with Dr. Dempsey as to the proper qualifications for a person to be a POSITA.
- 14. At their core, the underlying technology of the patents is related to electrophysiology and signal processing which is then used by doctors and other medical practitioners to treat mental health disorders. Therefore, it is my opinion that a POSITA at the time of the invention would have been someone having knowledge and familiarity with electrophysiology and signal processing. Sufficient familiarity and experience with the subject matter of the asserted patents could be obtained by: (i) successfully completing a Bachelor's degree in Electrical Engineering or Biomedical Engineering or similar discipline with classes or experience directed to electrophysiology and signal processing and TMS; (ii) a medical degree

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focusing on treatment of patients with brain disorders and experience with EEG and application of electrical or magnetic energy such as TMS; or (iii) at least three (3) years of experience in a job working with patients having brain disorders using treatment protocols involving TMS and EEG/electrophysiology.

- 15. At a minimum, I disagree with Dr. Dempsey that it is acceptable for a POSITA to have advanced training and experience in use of <u>either</u> EEG <u>or</u> TMS technology. The nature of the technology disclosed and claimed in the Asserted Patents requires a POSITA to have adequate experience with at least TMS and preferably, also EEG, to properly understand the subject matter of the Asserted Patents. Based upon Dr. Dempsey's Curriculum Vitae attached to his Dempsey Declaration, and the articles that Dr. Dempsey has authored, it is not apparent to me that Dr. Dempsey <u>has any</u> experience in technology relating to TMS and does not appear to have <u>anv</u> experience with EEG.
- I further understand that the '111 Patent is directed to "non-EEG biological 16. metrics". Thus, Dr. Dempsey's assertion that "advanced training and experience in the use of . . . EEG . . . technology" would not qualify him as a POSITA to opine regarding the '111 Patent.
- 17. In addition, I disagree with Dr. Dempsey that it is sufficient to have a degree in mental health or a related field with substantially similar courses, and 3-4 years of work experience. According to his Curriculum Vitae, Dr. Dempsey has undergraduate and graduate degrees in Psychology and a Doctorate of Philosophy in Clinical Psychology, but does not appear to have any experience relating to EEG or TMS, which is the subject of the Asserted Patents. Consequently, while Dr. Dempsey appears to be qualified as a clinical psychologist, it is my opinion that Dr. Dempsey lacks the requisite experience and qualifications to be a POSITA in connection with the Asserted Patents.

V. CLAIM CONSTRUCTION PRINCIPLES

18. The claim construction principles that I have been asked to apply are set forth in detail in my Declaration in support of Wave's Opening Claim Construction Brief [Dckt. # 32-5] ("Opening Bikson Declaration"), which is incorporated herein by reference.

VI. TECHNICAL BACKGROUND

- 19. In my Opening Bikson Declaration, I provided a detailed summary of the technical background of the Asserted Patents, which is incorporated herein by reference. However, as a courtesy to the Court, I have included herein a brief technical description of each of the Asserted Patents.
- 20. The '408 Patent provides a method and a device for use in treating a number of mental health disorders, by gently tuning the brain and affects symptoms of the mental health disorders without the use of medication, using a magnetic field to influence an intrinsic frequency within a specified EEG band, a Q-factor of the intrinsic frequency within a specified EEG band, a coherence value within the specified EEG band, or an EEG phase of the specified EEG frequency of the subject toward a pre-selected or target intrinsic frequency within the specified EEG band, Q-factor of the intrinsic frequency within a specified EEG band, coherence value within the specified EEG band, or EEG phase of the specified EEG frequency, respectively.
- 21. The '737 Patent provides a method for a novel, inexpensive, and easy to use therapy for a number of mental health disorders that gently tunes the brain and affects mood, focus, and cognition of a subject, by using a magnetic field to influence an intrinsic frequency within a specified EEG band or a Q-factor of the intrinsic frequency within a specified EEG band of the subject toward a pre-selected or target intrinsic frequency within the specified EEG band or Q-factor of the intrinsic frequency within a specified EEG band, respectively.
- 22. The '490 Patent provides a system for treating mental health disorders that gently tunes the brain, by using a magnetic field to move an intrinsic frequency within a specified EEG band, a Q-factor of the intrinsic frequency within a specified EEG band, a coherence value within the specified EEG band, or an EEG phase of the specified EEG frequency of the subject toward a pre-selected or target intrinsic frequency within the specified EEG band, Q-factor of the intrinsic frequency within a specified EEG band, coherence value within the specified EEG band, or EEG phase of the specified EEG frequency, respectively.

23. The '111 Patent provides a method for improving a physiological condition or a neuropsychiatric condition of a human mammal by subjecting the human to repetitive transcranial magnetic stimulation ("rTMS") at the frequency or pulse rate of a non-EEG biological metric or harmonic or sub-harmonic of the metric, which is chosen based on the cognitive element or symptom that is targeted and designed to be closest to a desired EEG frequency.

VII. "[A METHOD OF] IMPROVING A PHYSIOLOGICAL CONDITION OR A **NEUROPSYCHIATRIC CONDITION"**

24. I understand that the Defendant disagrees with Wave's proposed construction of the phrase "[A method of] improving a physiological condition or a neuropsychiatric condition" as that phrase appears in Claim 1 of the '111 Patent. The Parties' proposed constructions are set forth in the chart below.

Claim Term/Phrase	Plaintiff's Construction	Defendant's Construction
[A method of] improving a physiological condition or a neuropsychiatric condition	to make or become better [the medical conditions in the claim]	Indefinite and unpatentable subject matter.
'111 Patent, claim 1		

It is my opinion that a POSITA would understand the phrase "[A method of] improving a physiological condition or a neuropsychiatric condition" as Wave has proposed. This opinion is well supported by the intrinsic evidence as exemplified by the specification and prosecution history and the industry usage.

25. In my opening Bikson Declaration I established that the intrinsic evidence strongly weighs in favor of Wave's proposed construction. See Dkt. 32-5, Opening Bikson Declaration, p. 14-18. For example, I pointed to 10 different passages from the specification of the '111 Patent that favor Wave's proposed construction. *Id.* The passages from the specification include: (i) clear and consistent usage of the claim phrase, (ii) clinical assessments providing a baseline against which the treatment's effectiveness in reducing the patient's

symptoms for the conditions can be measured after treatment, and (iii) three specific clinical examples. Id.

- 26. During prosecution of the '111 Patent, the Examiner had no trouble understanding the phrase "[A method of] improving a physiological condition or a neuropsychiatric condition" in the claims. Upon reading the claim, the Examiner rejected the claim, citing other terms contained therein that he identified as indefinite. See Dkt. 32-8, '111 Prosecution History, at p. *62 (Oct. 21, 2016 Non-Final Office Action, p. 2). Given that the Examiner identified other claim terms within the subject claim as indefinite (which were subsequently amended to overcome the indefiniteness rejection), if the Examiner believed that the phrase "[A method of] improving a physiological condition or a neuropsychiatric condition" in the subject claims were indefinite, it is my opinion that he would have also rejected this phrase as being indefinite, in the same or a subsequent Office Action. The fact that he did not do so, indicates that the Examiner did not believe that this phrase was indefinite.
- 27. In my Opening Bikson Declaration, I also established that: (1) the term "improving" is commonly used in psychiatric and neurological research, (2) the word "improves" was construed in U.S. Patent No. 9,446,259, and (3) a Google Scholar search of "transcranial magnetic stimulation" and "improving" between the time period 1980 and 2012 returned 8,940 results. See Dkt. 32-5, Opening Bikson Declaration, p. 6-7.
- Independent of the evidence contained within the prosecution history of the '111 28. Patent, I understand that Defendant uses "improving" on its own website to describe the benefit patients receive from the advertised TMS treatments being offered. Defendant's website (www.brainfrequency.ai) repeatedly uses the term "improving" consistent with Wave's proposed construction in this case: "The Brain FrequencyTM AI system is an innovative therapeutic approach to improving brain health and wellness." Dkt. 32-3 (emphasis added).
- 29. Defendant's website further states that "TMS treatment has traditionally been used to manage depression. However, TMS therapy does not use qEEG to tailor treatment plans to individual needs. Brain FrequencyTM is an individualized approach to TMS and is more

effective as each patient's brain has a unique frequency needed for optimal performance. Brain FrequencyTM has dramatically improved the treatment of patients with major depressive disorders, post-traumatic stress, TBI, anxiety, addictive disorders, ADHD, sleep disorders, and OCD." Dkt. 32-3 (emphasis added).

- 30. Such references to "improving" appearing on Defendant's own website today are instructive of the fact that Defendant and researchers, like a POSITA and a lay person, clearly understand the meaning of the term "improving" in the context of the technology disclosed and claimed in the '111 Patent and the benefits received from patients obtaining such treatment.
- 31. In addition, although Dr. Dempsey is not a POSITA in my opinion, even in his area of specialty he uses the term "improve" to have the same meaning – to make or become better the medical conditions in the claim. For example, the front page of his website (trac9.com) references podcasts featuring Jared P. Dempsey, Ph.D., which purport to relate to "Improved Outcomes Through Feedback-Informed Clinical Care. Tache Dec., ¶ 10 (emphasis added).
- 32. This mention of "[i]mproved" is not merely an isolated instance. The front page of his website further proclaims that his platform uses data-driven clinical case assignment in which "[i]ndividualized case assignment is vital to **improving** clinical efficacy and client outcomes." Attached as Exhibit 3, trac9 Informatics (https://trac9.com) (last accessed May 31, 2024), at p. 3 (emphasis added). The front page of his website also proclaims comprehensive assessments that measure "variables that best predict long-term, sustained recovery [that] allows providers to track improvement, optimize individual treatment plans and evaluate program efficacy." Ex. 3, p. 7 (emphasis added).
- 33. Nor is Dr. Dempsey's usage of improved on the front page of his website merely an oversight. The other sections of the website similarly reference "improve" and variations of the word. For example, a section of the Trac9 website entitled "Spotlight: Windmill Wellness Ranch" discloses:

Shannon described how Windmill Wellness Ranch has not only adopted Trac9,

but also utilizes it to its fullest potential, this in combination with her cutting-edge use of Brain FrequencyTM results in higher patient **improvement** rates, more intentional and guided clinical management, and even changes in the way that they navigate daily treatments. Attached as Exhibit 4, trac9 Informatics, (https://trac9.com/spotlight-windmill-wellness-ranch/) (last accessed May 31, 2024), at p. 2 (emphasis added).

34. The same section of the Trac9 website further discloses:

Trac9's clinical tracking software plays a huge part in not only managing this information but by allowing practitioners to access the information and use it practically. By centralizing a patient's diagnostic, clinical, and therapeutic data into a single place, Windmill Wellness Ranch has been able to dramatically **improve** both patient and clinical outcomes. Ex. 4, at p. 2 (emphasis added).

- Therefore, Dr. Dempsey's own website uses the word "improve" in several 35. different places and uses the word with consistency to mean "to make or become better the medical conditions in the claim." The fact that Dr. Dempsey's own website also references Brain Frequency is further proof that Defendant understands the meaning of the word.
- 36. In addition to his website, Dr. Dempsey's articles further support Wave's proposed construction of the word "improve" and its variants. In one article by Dr. Dempsey, the very first line of the Abstract discloses: "Investigation of relationship patterns between cooccurring symptoms has greatly **improved** the efficacy of psychiatric care." Dempsey, J. P., Randall, P. K., Thomas, S. E., Book, S. W., & Carrigan, M. H. (2009). Treatment of social anxiety with paroxetine: mediation of changes in anxiety and depression symptoms. Comprehensive Psychiatry, 50(2), 135-141.
- 37. Based on the foregoing, a POSITA would clearly understand that "improved" means to make or become better [the medical conditions in the claim], as Wave has proposed. For example, a patient that has Alzheimer's would have an improved memory and a patient struggling with pain would have decreased pain. In other words, the symptoms associated with a particular condition would be made better.
- 38. In summary, as set forth in my Opening Bikson Declaration, a POSITA would understand the meaning of "[A method of] improving a physiological condition or a neuropsychiatric condition" to be synonymous with make or become better [the medical

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conditions in the claim, as proposed by Wave. Dkt. 32-5, p. 5-13. Furthermore, as established above, a POSITA would understand the meaning of the phrase and the scope of the claims in which it appears with reasonable certainty. Even though Dr. Dempsey is not a POSITA, the industry usage of the word "improve" by him and Defendant establishes that the word is intended to have a clear meaning that would be ascertained by a POSITA without difficulty.

"INTRINSIC FREQUENCY" VIII.

39. I understand that Defendant disagrees with Wave's proposed construction of the term "intrinsic frequency" as that term appears in claim 1 of the '490 Patent, claims 1-2, 12, and 20 of the '408 Patent, claims 3 and 7 of the '111 Patent, and claims 1-2 and 4 of the '737 Patent. The Parties' proposed constructions are set forth in the chart below.

Claim Term/Phrase	Plaintiff's Construction	Defendant's Construction
Intrinsic frequency	frequency selected to which	The frequency (f ₀) at which
munisic nequency	treatment is to be applied	peak signal power in the
'490 Patent, Claim 1		specified band (Emax) is located
'408 Patent, Claims 1-2, 12, 20		For '111 Patent: Indefinite &
'111 Patent, Claims 3, 7		Invalid: Not enabled/lacking
'737 Patent, Claims 1-2, 4		written description
		or
		In the alternative: "the
		frequency (f0) at which peak
		signal power in the specified
		band (Emax) is located"

- 40. Wave's proposed construction of the claim term "intrinsic frequency" would be well understood by a POSITA. Wave's proposed construction is consistent with the claim language, the specification, and the prosecution history and uses plain English.
- 41. According to my understanding of the applicable claim construction principles, the intrinsic evidence (i.e., the claim language, the specification, and the prosecution history) is key in determining the meaning of a claim term. As shown in my Opening Bikson Declaration, the claim language and the specification establishes that Wave's proposed construction is the

proper construction. See Dkt.32-5, Opening Bikson Declaration, p. 13-21. By way of example, I quoted 13 passages from the specifications of the Asserted Patents – all of which are consistent in showing that the meaning of intrinsic frequency is a "frequency selected to which treatment is to be applied."

42. The prosecution history for the Asserted Patents confirms that the Examiner well understood the meaning of the term intrinsic frequency. For example, the prosecution history of the '408 Patent discloses:

Further, Claim 2 of the present invention recites adjusting output of a magnetic field and influencing the subject's intrinsic frequency in a specified EEG band toward a pre-selected intrinsic frequency of the same EEG band. On the other hand, Katz's only intention and goal is to move a subject from a current brain state into a desired brain state. Since the brain states correlate to separate EEG bands in Katz (i.e. from relaxed in the alpha band to sleep in the delta or theta band), Katz' methods and devices move the brain waves from one band to another."

Dkt. 029-07,'408 Prosecution History at *800 (September 10, 2012 Amendment in Response to Final Office Action, p. 8) (italics in original).

43. The '737 Prosecution History discloses:

In regards to claims 1 and 2, the prior art of record does not teach or suggest a method as claimed by Applicant, that includes the step of moving at least one of an intrinsic frequency of a specified EEG band of the subject toward a preselected intrinsic frequency of the specified EEG band and a O-factor of an intrinsic frequency within a specified EEG band of the subject toward a preselected Ofactor using said magnetic field.

Dkt. 029-09, '737 Prosecution History at *1508 (March 25, 2014, Final Office Action, p. 5).

44. In the prosecution history for the '490 Patent, in responding to the first Office Action issued on 9/23/13, dependent Claim 18 was amended to describe that the intrinsic frequency can be any frequency between 0.5 Hz and about 100 Hz in increments of about 0.1 Hz. Other than this amendment, the intrinsic frequency was not addressed in the file history for the '490 Patent. Dkt. 029-08, '490 Prosecution History at *1526 (Mar. 19, 2014 Office Action

Response, p. 4).

- 45. In the prosecution history for the '111 Patent, the Examiner understood the meaning of intrinsic frequency, although the term was the subject of a rejection for lack of antecedent basis which was corrected. *See e.g.*, Dkt. 029-6, '111 Prosecution History at *62 (Oct. 21, 2016 Non-Final Rejection) and *id.* at *127-133 (June 27, 2017 Final Rejection). Because the Examiner did not reject the claim term for reasons beyond antecedent basis, the Examiner clearly understood the meaning of the claim term. In addition, because the Examiner did not reject the claim term for indefiniteness after the lack of antecedent basis was corrected, it is my opinion that the Examiner clearly understood the meaning of the claim term.
- 46. As also set forth in the Opening Bikson Declaration, a POSITA would understand the meaning of "intrinsic frequency" as proposed by Wave. *See* Dkt. 32-5, p. 13-21. Furthermore, a POSITA would understand the meaning of the phrase and the scope of the claims in which it appears with reasonable certainty. A Google Scholar search for "intrinsic frequency" and "TMS" between 1980 and 2012 returns 97 results, which clearly establishes that intrinsic frequency was commonly used and well-known in the art.
- 47. In Defendant's Opening Claim Construction Brief, it argued that the use of the claim term "intrinsic frequency" lacks written description. *See* Defendant's Opening Claim Construction Brief, p. 10. This argument is wrong. The '111 Patent references the claim term "intrinsic frequency" 14 times in a clear and consistent way.
- 48. For example, the '111 Patent discloses, "Various bodily functions operate at frequencies that are harmonics or sub-harmonics of the brain's **intrinsic frequency**." '111 Patent, 2:38-40. The '111 Patent further discloses: "

For example, if an autistic patient has a heart rate of 1.5 Hz and the patient's intrinsic alpha brain waves cannot be determined then the rTMS treatments are initially set to the 6th harmonic or 9 Hz. The patient is treated at this frequency until an intrinsic alpha brain wave frequency is established. rTMS treatments are then continued at the **intrinsic frequency**. (emphasis added).

Therefore, the '111 Patent does reference intrinsic frequency.

- 49. Not only does the '111 Patent reference "intrinsic frequency," but, in my opinion, "intrinsic frequency," as of the priority date for the '111 Patent on April 6, 2012, had become well-known to a POSITA. This increased knowledge concerning "intrinsic frequency" occurred in the approximately 4 years after the priority date for the '490 Patent and '737 Patent on September 24, 2008. A Google Scholar search for "intrinsic frequency" between 2008 and 2012 returns 51 results. A Google Scholar search for "intrinsic frequency" between 2004 and 2008 returns 30 results. Thus there was an acceleration in the number of articles published relating to "intrinsic frequency" and "TMS" in the four years preceding the priority date for the '111 Patent - thus confirming that "intrinsic frequency" had become a well-known term in the field.
- 50. Defendant also argues that the specification of the '111 Patent refers to the intrinsic frequency as a range while the claims refer to it as a single frequency in a given band. See Defendant's Opening Claim Construction Brief, p. 10. While not providing any opinion as to the scope of the claims containing the claim term "intrinsic frequency", the references to ranges contained within the specification merely point out the ranges that the intrinsic frequency can be selected from in the specific examples provided. As a POSITA, I would view the term "intrinsic frequency" contained within the subject claims to be consistent with the description thereof contained within the specification, rather than in conflict therewith as asserted by Defendant.
- 51. In my opinion, Defendant has taken quotes out of context because many of the selected quotes are no more than 5 words in length. For example, Defendant references "Delta band intrinsic frequency (<4 Hz)," "Theta band intrinsic frequency (4-8 Hz)," "Alpha band intrinsic frequency (8-13 Hz)," "Beta band intrinsic frequency (13-30 Hz)," and the like as evidence that intrinsic frequency is confusingly a range. *Id.* The patent discloses, in context:

The frequency chosen is preferably a harmonic of the heartbeat that is closest to an **interested frequency** that may be associated with the disorder, symptom, cognitive characteristic or physical condition of interest. Frequencies of interest include the following:

- a. Delta band intrinsic frequency (<4 Hz).
- b. Theta band intrinsic frequency (4-8 Hz).

- c. Alpha band intrinsic frequency (8-13 Hz).
- d. Beta band intrinsic frequency (13-30 Hz).

This passage clearly references an "interested frequency" (not an "interested frequency range"), "[f]requencies of interest" (not "frequency ranges of interest"), and references Delta band intrinsic **frequency** (< 4 Hz), Theta band intrinsic **frequency** (4-8 Hz), Alpha band intrinsic **frequency** (8-13 Hz), Beta band intrinsic **frequency** (13-30 Hz), among others. These ranges are provided to illustrate where the frequencies of interest can be selected from. For example, "Delta band intrinsic frequency (< 4 Hz)" merely means that the intrinsic frequency is a delta band intrinsic frequency because the intrinsic frequency is selected from the delta band. The delta band is the range of < 4 Hz. A POSITA understands that the delta band refers to the frequency range of less than 4 Hz and would understand that when an intrinsic frequency is in the delta band, the intrinsic frequency is selected from a specific range – the delta range. In addition, the second word of the term "intrinsic frequency" is frequency. It is not confusing to understand the intrinsic frequency to be a frequency and not a frequency range.

- 52. As set forth in my Opening Bikson Declaration, Defendant's proposed construction is drawn from an isolated instance from the specifications for the '490 Patent, the '408 Patent, and the '737 Patent that is directed to the "Q-factor", <u>not</u> the "intrinsic frequency". *See* Dkt. 32-5, at p. 19-21. Therefore, Defendant's proposed construction is flawed for this reason alone.
- 53. It is my understanding that Defendant asserts that Claim 2 of the '408 Patent would not make sense in light of Wave's proposed construction. *See* Dkt. 34, Defendant's Opening Claim Construction Brief, at p. 8-9. However, to support its argument, Defendant failed to use what I understand is a previously agreed-upon construction for the claim term "preselected intrinsic frequency" as "[a] targeted intrinsic frequency chosen before treatment." When the agreed construction for "pre-selected intrinsic frequency" is used, Defendant's argument fails.

- 54. It is my understanding that Defendant also argues that Plaintiff's proposed construction conflicts with other limitations because Claim 1 of the '408 Patent also recites moving "a specified EEG frequency." As a POSITA, it is my opinion that this argument is based upon Defendant's failure to understand the language of the claim as a whole.
- 55. Without providing any opinion as to its claim scope, as a POSITA, I understand Claim 1 of the '408 Patent to disclose 4 alternative limitations involving intrinsic frequency, Qfactor, coherence value, and EEG phase. "A specified EEG frequency" is disclosed in relation to the EEG phase – which is a different, alternative, limitation from the limitation involving intrinsic frequency. The difference is notable because unlike the intrinsic frequency, Q-factor, and coherence value, which are analyzed in the frequency domain, in these patents the EEG phase is analyzed in the time domain. That is, EEG phase is a comparison of the timing of two waveforms and is analyzed with respect to a frequency (i.e., the specified EEG frequency). Once the meaning of the language of Claim 1 is properly understood, it is my opinion that Defendant's argument is without merit.
- In addition, Dr. Dempsey asserts that the term intrinsic frequency "is not a term of 56. art and has no ordinary meaning." Dkt. 34-1, Dempsey Declaration, p. 7. Dr. Dempsey specifically states that "as with the case with the '111 Patent, a POSITA would not know what the meaning of intrinsic frequency as [sic] it is not defined in that patent." *Id.* at p. 6. Dr. Dempsey appears to ignore important evidence such as the fact that: (i) the Examiners for these patents, including the '111 Patent, had no trouble ascertaining the meaning of "intrinsic frequency," and (ii) the claim term "intrinsic frequency" is commonly used in the art and well understood by a POSITA.
- 57. In summary, a POSITA would understand the meaning of the claim term with reasonable certainty and it is my opinion that Wave's proposed construction is properly supported by and consistent with the intrinsic evidence of the subject Patents.

"Q-FACTOR" IX.

58. I understand that the Defendant disagrees with Wave's proposed construction of the term "Q-factor" as that term appears in Claim 1 of the '490 Patent, Claims 1-2, 12, and 20 of the '408 Patent, and Claims 1-2 and 4 of the '737 Patent. The Parties' proposed constructions are set forth in the chart below.

Claim Term/Phrase	Plaintiff's Construction	Defendant's Construction
Q-factor	Plain and ordinary meaning,	Ratio of $f0/\Delta f$, where f0 is the
Q-lactor	namely where the Q-factor is	intrinsic frequency and Δf is the
'490 Patent, Claim 1	the ratio of the intrinsic	frequency bandwidth for which
'408 Patent, Claims 1-2, 12,	frequency relative to the	the energy is above one-half the
20 20	frequency bandwidth at half	peak energy in the specified
'737 Patent, Claims 1-2, 4	peak energy.	band.

- 59. I understand that Defendant does not argue that Q-Factor is indefinite. Instead, it only seeks to construe the term.
- 60. Wave's proposed construction of "Q-factor" would be well understood by a POSITA. Based upon my understanding that the intrinsic evidence is key in determining the propriety of claim construction, the claim language, the specification, and the prosecution history should be examined to determine the proper construction of the claim term "Q-factor". According to the intrinsic evidence, Wave's proposed construction is fully supported by the intrinsic evidence and, in contrast to Defendant's proposed construction, is helpful to the jury since it is not overly technical. Specifically, Defendant's proposed construction uses symbols that are not present in the vast majority of the disclosures of "Q-factor" in the '490 Patent, the '408 Patent, and the '737 Patent.
 - 61. Claim 1 of the '490 Patent recites in part:
 - a) a non-transitory computer readable medium containing a subject data value comprising

. . .

ii) a Q-factor of the first intrinsic frequency,

. . .

b) a processor configured to control the magnetic field based on said subject data value, wherein the magnetic field is configured to

. . .

ii) move the Q-factor of the first intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using the magnetic field,

. .

Claim 1 of the '490 Patent does not use the symbols "f₀" or "Δf" and simply uses the terms "Q-factor" and "first intrinsic frequency."

- 62. Claims 1-2, 12, and 20 of the '408 Patent similarly avoid the use of symbols "f₀" or "Δf" in connection with the claim term "Q-Factor". Claim 1 of the '408 Patent recites in part: "move a Q-factor of the intrinsic frequency toward a target Q-factor of the intrinsic frequency using the magnetic field...." Claim 2 of the '408 Patent recites in part: "comprising moving at least one of ... a Q-factor of the intrinsic frequency toward a target Q-factor of the intrinsic frequency...." Claim 12 of the '408 Patent recites in part: "wherein the first processor or a second processor moves at least one of:..(b) a Q-factor of an intrinsic frequency of the brain of the subject within a specified EEG band to a target Q-factor of the intrinsic frequency using the magnetic field...." Claim 20 of the '408 Patent recites in part: "wherein said information comprises at least one of items listed below: ... (b) the Q-factor of the intrinsic frequency...."
- 63. Furthermore, Claims 1, 2, and 4 of the '737 Patent also omit the use of the symbols "f₀" or "Δf" in connection with "Q-factor." Claim 1 of the '737 Patent recites in part: "a Q-factor of an intrinsic frequency within a specified EEG band of the subject toward a preselected Q-factor...wherein the pre-selected Q-factor is a Q-factor that increases blood flow in the cortex of the subject."
- 64. Because the claims that use the term Q-factor do not use the symbols " f_0 " or " Δf ", a POSITA would understand the term Q-factor without the need to use such symbols, consistent with the construction for "Q-factor" Wave has proposed.
- 65. The specifications for the '490 Patent, '408 Patent, and '737 Patent further support this interpretation. Although the specification includes a few instances where reference to the symbols " f_0 " or " Δf " are used in describing the Q factor, the vast majority of the references to Q factor avoid the use of these symbols.
 - 66. For example, the '408 Patent discloses:

In another aspect are methods of modulating the electrical activity of a brain in a subject in need thereof, comprising: (a) adjusting output of a magnetic field for influencing a **Q-factor**, a measure of frequency selectivity of a specified EEG

band, of the subject toward a target **Q-factor** of the band; and (b) applying said magnetic field close to a head of the subject. '408 Patent 2:1-6. (emphasis added).

67. For example, the '408 Patent also discloses, without using symbols:

In another aspect are methods of modulating the electrical activity of a brain in a subject in need thereof, comprising: (a) adjusting output of a magnetic field for influencing a **Q-factor**, a measure of frequency selectivity of a specified EEG band, of the subject toward a target **Q-factor** of the band; and (b) applying said magnetic field close to a head of the subject. In another aspect are methods of modulating the electrical activity of a brain in a subject in need thereof, comprising: determining the **Q-factor** of the intrinsic frequency within the specified EEG band of the subject; comparing the **Q-factor** of the intrinsic frequency from step (a) to an average **Q-factor** of the intrinsic frequency of a control group; if the Q-factor of the intrinsic frequency from step (a) is higher than the average **Q-factor** of the intrinsic frequency of the control group, tuning down the **Q-factor** of the intrinsic frequency of the subject by applying a magnetic field with a plurality of frequencies or with a single target frequency close to a head of the subject; and if the **Q-factor** of the intrinsic frequency from step (a) is lower than the average **Q-factor** of the intrinsic frequency of the control group, tuning up the **Q-factor** of the intrinsic frequency of the subject by applying a magnetic field with a target frequency to a head of the subject. '408 Patent 17:62-18:17. (emphasis added).

68. Another example similarly discloses the Q-factor without using the symbols "f₀" or " Δf ". The '408 Patent discloses:

Disclosed herein, in certain embodiments, are methods of improving cognitive performance by modulating the electrical activity of a brain in a subject in need thereof, comprising: (a) adjusting output of a magnetic field for influencing a Qfactor, a measure of frequency selectivity of a specified EEG band, of the subject toward a target **Q-factor** of the band; and (b) applying said magnetic field close to a head of the subject. In some embodiments, the subject's **Q-factor** is adjusted to its natural level. In another aspect are methods of modulating the electrical activity of a brain in a subject in need thereof, comprising: determining the Qfactor of the intrinsic frequency within the specified EEG band of the subject; comparing the **Q-factor** of the intrinsic frequency from step (a) to an average **Q**factor of the intrinsic frequency of a control group; if the Q-factor of the intrinsic frequency from step (a) is higher than the average **Q-factor** of the intrinsic frequency of the control group, tuning down the **Q-factor** of the intrinsic frequency of the subject by applying a magnetic field with a plurality of frequencies or with a single target frequency close to a head of the subject; and if the **Q-factor** of the intrinsic frequency from step (a) is lower than the average **Q**factor of the intrinsic frequency of the control group, tuning up the Q-factor of the intrinsic frequency of the subject by applying a magnetic field with a target

frequency to a head of the subject. '408 Patent 26:24-48. (emphasis added).

69. The '490 Patent and the '737 Patent similarly disclose the Q-factor without using the symbols " f_0 " or " Δf ". For example, the '490 Patent discloses:

In another aspect are methods of treating a subject, comprising: determining the Q-factor of the intrinsic frequency within the specified EEG band of the subject; comparing the Q-factor of the intrinsic frequency from step (a) to an average Q-factor of the intrinsic frequency of a healthy population database; if the Q-factor of the intrinsic frequency from step (a) is higher than the average Q-factor of the intrinsic frequency of the healthy population database, tuning down the Q-factor of the intrinsic frequency of the subject by applying a magnetic field with a plurality of frequencies or with a single pre-selected frequency close to a head of the subject; and if the Q-factor of the intrinsic frequency from step (a) is lower than the average Q-factor of the intrinsic frequency of the healthy population database, tuning up the Q-factor of the intrinsic frequency of the subject by applying a magnetic field with a pre-selected frequency to a head of the subject. '490 Patent, 6:32-47; see also '737 Patent, 6:29-44 (similar).

- 70. In contrast, the patents disclose with respect to an <u>example</u> of the Q factor:
- FIG. 12 shows an **example of the Q-factor** as used in this invention. The figure shows a sample graph of the frequency distribution of the energy of an EEG signal. It can be seen that a frequency range, Δf can be defined as the frequency bandwidth for which the energy is above one-half the peak energy. The frequency f0 is defined as the intrinsic frequency in the specified band. The Q-factor is defined as the ratio of $f_0/\Delta f$. As can be seen, when ΔF decreases for a given f0, the Q-factor will increase. This can occur when the peak energy Emax of the signal increases or when the bandwidth of the EEG signal decreases. '408 Patent 15:49-59. See also '490 Patent 22:19-29; '737 Patent 20:30-41 (emphasis added).

Therefore, in an isolated example with respect to FIG. 12, the Q-factor is used in reference to the symbols " f_0 " or " Δf ". However, the vast majority of references to the Q-factor do not use these symbols. That is, the references to the Q factor that do not specifically refer to FIG. 12 (in the specifications for the '490 Patent, '408 Patent, and '737 Patent) do not use the symbols " f_0 " or " Δf ".

71. The prosecution history for the '408 Patent and the '490 Patent further illustrates that the Q-factor should be referenced without using the symbols " f_0 " or " Δf ". For example, the '408 prosecution history discloses:

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Also with respect to Claim 1, since Katz is concerned with moving the current brain state to another brain state, Katz fails to teach or suggest "adjusting output of a magnetic field to a setting that is operable to ... influence a Q-factor of the intrinsic frequency toward a target Q-factor." As described and shown in the instant specification (for example at paragraphs [0313], and in Figure 12, at least), a Q-factor is a measure of the distribution around the frequency within a single EEG band. '408 Prosecution History at *737. See also '408 Prosecution History at *1746-47 (similar statement); '490 Prosecution History at *1530 (stating similar); '490 Prosecution History at *1804 (stating similar).

- 72. The prosecution history for the '737 Patent also uses the Q-factor without referencing the symbols "f₀" or "Δf". The '737 prosecution history discloses: "Q-factor is being interpreted as the bandwidth about a center frequency. '408 Prosecution History at *658. See also '490 Prosecution History at *1625 (stating similar); '737 Prosecution History at *1102 (stating similar).
- 73. Therefore, the vast majority of the intrinsic evidence shows that the Q-factor is disclosed without using the symbols " f_0 " or " Δf ". It is my opinion that the construction of the claim term Q-factor should not include these symbols as it does not add any clarity as to the meaning of the term (as evidenced by its frequent use without the symbols) and may cause confusion among a jury that does not understand these symbols as they are not part of ordinary language used by a lay person.
- 74. It is my understanding that Defendant has also asserted that Q-factor does not have a plain and ordinary meaning. A Google Scholar search of "Q-factor" and "TMS" between 1980 and 2008 provides 297 results. Therefore, at the time of filing of the patents, the Q-factor was a term commonly used by a POSITA and, as such, did have a plain and ordinary meaning that a POSITA would understand.
- 75. In its proposed construction of "Q-factor", Defendant rearranged the wording in a way that is inconsistent with the intrinsic evidence. Defendant asserts that Q-factor should be construed as "[r]atio of $f_0/\Delta f$, where f_0 is the intrinsic frequency and Δf is the frequency bandwidth for which the energy is above one-half the peak energy in the specified band." (emphasis added). But the specification actually discloses "in the specified band" in relation to

the intrinsic frequency and not in relation to the one half the peak energy.

- 76. For instance, the specification of the '408 Patent discloses: "It can be seen that a frequency range, Δf can be defined as the frequency bandwidth for which the energy is above one-half the peak energy. The frequency f_0 is defined as the intrinsic frequency in the specified band." (emphasis added). Therefore, Defendant has rearranged the wording in a way that is inconsistent with the specification by moving "in the specified band" to the end of the sentence ending "for which the energy is above one-half the peak energy." In my opinion, Defendant rearranged the words to give them a different meaning from that intended in the specification. I did not see any explanation for this change in either Dr. Dempsey's declaration or Defendant's Opening Claim Construction Brief.
- I have also been informed that one of the key purposes of claim construction is for 77. a claim term to be construed in plain English so that it can be understood by a jury. Including unfamiliar symbols such as " f_0 " and " Δf " into the construction of "Q-factor" would be contrary to such a key objective. Because the main difference between Wave's proposed construction and Defendant's proposed construction is the use of the symbols " f_0 " and " Δf ", it is my opinion that Wave's proposed construction should be adopted, both because it is consistent with the ample available intrinsic evidence and because it is in plain English and would be readily understood by a jury.
- 78. As a professor, my duties involve explaining complicated concepts to students and, at times, the lay public. Although using the symbols " f_0 " or " Δf " makes sense in academic settings, inclusion of the symbols " f_0 " or " Δf " is likely to confuse members of the lay public. For instance, the symbol "f₀" uses a subscript. A member of the lay public is not likely to understand the meaning of the subscript absent explanation. In addition, the symbol " Δf " uses the symbol "Δ" which is the Greek letter "delta." A member of the lay public is not likely to understand what the " Δ " means absent explanation and why a Greek letter is affixed to the prefix of "f". Inclusion of symbols that probably require an explanation would not be helpful to members of the jury.

79. In summary, Wave's proposed construction for Q-factor would be wellunderstood by a POSITA and Defendant's construction for Q-factor should not be adopted because its construction is taken from an isolated portion of the specification and is not even quoted correctly. In addition, Defendant's proposed construction includes the use of symbols that would not be readily understood by a jury.

X. "COHERENCE VALUE"

80. I understand Defendant disagrees with Wave's construction of the term "coherence value" as that term appears in Claim 1 of the '490 Patent and Claims 1, 12, and 20 of the '408 Patent. The Parties' proposed constructions are set forth in the chart below.

Claim Term/Phrase	Plaintiff's Construction	Defendant's Construction
Coherence value	Not indefinite or invalid.	Indefinite and Invalid: Not enabled/lacking written
'490 Patent, Claim 1 '408 Patent, Claims 1, 12, 20	Plain and ordinary meaning namely a measure of similarity between two or more signals over time.	description or in the alternative: "The difference between the frequency and phase of two waves."

- 81. Coherence has a meaning that is well-known in mathematics and has been used for decades and continues to be used in mathematics. See e.g., William A. Gardner. A unifying view of coherence in signal processing. Signal Processing, 29:113-140 (November 1992). Furthermore, "value" merely refers to a number that is the result of a calculation. Attached as Exhibit 5, Merriam-Webster OnLine (https://web.archive.org/web/20060512184013/https://www.merriamwebster.com/dictionary/value) (last visited May 31, 2024).
- 82. Therefore, the claim term "coherence value" has a clear meaning that a POSITA would understand with reasonable certainty. The intrinsic evidence (i.e., claims, specification, and prosecution history) is consistent and clear in the meaning of the claim term "coherence value".
 - 83. Claim 1 of the '490 Patent and Claims 1, 12, and 20 of the '408 Patent provide

- a) a non-transitory computer readable medium containing a subject data value comprising
- iii) a **coherence value** of a second intrinsic frequency and a third intrinsic frequency, wherein the second and third intrinsic frequencies are from two different sites in the brain of the subject within the specified EEG band, or
- b) a processor configured to control the magnetic field based on said subject data value, wherein the magnetic field is configured to
- iii) move the **coherence value** by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to the head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value, or ... (emphasis added).
- 84. Without providing any opinion as to the scope of the subject claims, as used in the subject claims, as a POSITA I understand "coherence value" to mean a measure of similarity between two or more signals (e.g., the similarity between the signal measured at an intrinsic frequency from a first site in the brain of the subject and a second signal measured at an intrinsic frequency from a second site in the brain of the subject) over time. The coherence value can be moved by: (i) applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field, or (ii) applying the magnetic field and the second magnetic field that is synchronized with the magnetic field.
 - 85. Claim 1 of the '408 Patent recites in part:

move a **coherence value** of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value using the magnetic field wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to the head of the subject... (emphasis added).

86. According to Claim 1, the coherence value is a measure of similarity between two or more signals and can be moved by: (i) applying at least two asynchronous magnetic fields, or (ii) by applying at least one synchronized magnetic field.

- 87. Similarly, Claim 12 of the '408 Patent recites in part:
- wherein the first processor or a second processor moves at least one of:

. . .

- (c) a **coherence value** of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band using the magnetic field wherein if the coherence value is higher than a pre-selected coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the pre-selected coherence value, applying at least one synchronized magnetic field close to the head of the subject... (emphasis added).
- 88. According to Claim 12, the coherence value is a measure of similarity between two or more signals (e.g., providing multiple intrinsic frequencies) and can be moved by: (i) applying at least two asynchronous magnetic fields, or (ii) by applying at least one synchronized magnetic field.
- 89. Claim 20 of the '408 Patent recites in part: "wherein said information comprises at least one of items listed below: (a) the intrinsic frequency; (b) the Q-factor of the intrinsic frequency; (c) the **coherence value of intrinsic frequencies**; (d) the EEG phase; and (e) any combination thereof." (emphasis added). According to the claim, a coherence value is a measure of similarity between two or more signals.
- 90. Therefore, according to Claim 1 of the '490 Patent and Claims 1, 12, and 20 of the '408 Patent, "coherence value" is consistently used to indicate a measure of similarity between two or more signals over time.
- 91. The specification of the '408 Patent is similarly consistent in its usage of coherence value. The '408 Patent discloses:

Provided herein is a method of improving coherence of intrinsic frequencies within a specified EEG band among multiple locations of a brain of a subject, comprising determining the **coherence value of the intrinsic frequencies** among multiple locations throughout a scalp of the subject; comparing the coherence value from step (a) to an average coherence value of a control group; if the coherence value from step (a) is higher than the average coherence value of the

control group, lowering the coherence value of the subject by applying at least two asynchronous magnetic fields close to a head of the subject; if the coherence value from step (a) is lower than the average coherence value of the control group, raising the coherence value of the subject by applying at least one synchronized magnetic field close to a head of the subject. In some embodiments, a NEST device, such as one of the NEST devices (pMERT devices) described herein is used to create the magnetic field of the method. '408 Patent 41:35-51. (emphasis added).

This selection from the specification further illustrates that coherence value is a measure of similarity between two or more signals over time.

- 92. The specification for the '408 Patent provides examples in which the coherence value is of intrinsic frequencies of multiple locations in the brain of the subject. The '408 Patent discloses: "Coherence analysis is carried out between Fz and Pz in the peak alpha frequency." '408 Patent 52:37-38. Fz and Pz refer to different locations in the brain of a subject. The peak alpha frequency is a specific example of an intrinsic frequency. Therefore, this usage of coherence is consistent with the other uses of coherence value.
- 93. The '490 Patent is similarly consistent in its usage of coherence value. The '490 Patent discloses:

In another aspect are methods adjusting output of a magnetic field for influencing a coherence of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a pre-selected or target coherence value comprising: determining the coherence value of the intrinsic frequencies among multiple locations throughout a scalp of the subject; comparing the coherence value from step (a) to an average coherence value of a healthy population database; if the coherence value from step (a) is higher than the average coherence value of the healthy population database, lowering the coherence value of the subject by applying at least two asynchronous magnetic fields close to a head of the subject; if the coherence value from step (a) is lower than the average coherence value of the healthy population database, raising the coherence value of the subject by applying at least one synchronized magnetic field close to a head of the subject. '490 Patent 6:54-7:3. See also '490 Patent 31:51-67 (similar). (emphasis added).

This usage of coherence value is a measure of similarity between two or more signals.

94. The prosecution history further supports this usage of coherence value. The '408

prosecution history discloses:

The Examiner refers to a definition of "coherence" in the Office Action based on Katz. However, Applicants respectfully disagree with this characterization of the term based on the way the term is used in the claims and specification herein. Coherence, as used in the present application, refers to how closely matched are the intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band (e.g., how closely matched is a first intrinsic frequency of a first site in the brain of the subject within a specified EEG band to a second intrinsic frequency of a second site in the brain of the subject within the same EEG band, at least). (See, e.g. para [0169], at least). It is expressed as a coherence value. Thus, if the two or more intrinsic frequencies are matched in frequency, a coherence value shows this matching characteristic. Likewise, if the two or more intrinsic frequencies are not matched, the coherence value expresses this. A coherence value that is higher (more coherent) would indicate that the intrinsic frequencies are more closely matched than the situation in which a coherence value is lower (indicating less coherent). '408 Prosecution History at *738 (emphasis added).

The prosecution history indicates that the usage of the term "coherence value" in the claims and specification has a consistent and clear meaning. That is, coherence value is a measure of similarity between two or more signals over time. As a POSITA, I understand that because the claims are specifically referencing intrinsic frequencies, the coherence value is used with reference to intrinsic frequencies.

- 95. A Google Scholar search for "coherence value" and "TMS" between 1980 and 2008 returns 41 results which establishes that use of "coherence value" in the context of "TMS" was common and there was a plain and ordinary meaning for "coherence value" in the context of TMS that a POSITA would understand. Furthermore, a Google Scholar search for "coherence" and "TMS" between 1980 and 2008 returns 10,800 results which further establishes that "coherence" and "coherence value" were common terms that a POSITA would understand.
- I reviewed Dr. Dempsey's testimony regarding coherence value and identified 96. multiple issues. First, the Dempsey Declaration improperly partitions "coherence" from "value" and argues that each term has a meaning used in mathematics but somehow concludes that the combination of coherence and value would not have such a meaning. Dkt. 34-1, Dempsey Declaration, p. 7. This is inconsistent with decades of use of such terms as I noted above.
 - 97. Dr. Dempsey also argues that a POSITA would not be able to ascertain a

coherence value with reasonable certainty because different methods of calculation would allegedly lead to different results. Dkt. 34-1, Dempsey Declaration, p. 7. He is wrong on both accounts.

- 98. Dr. Dempsey refers to four different options for calculating coherence value : (1) magnitude-squared coherence, (2) phase-locking value, (3) wavelet coherence, and (4) partial coherence. *Id.*
- 99. Dr. Dempsey first references magnitude-squared coherence, which is one way of measuring the coherence value.
- 100. He next references phase-locking value, which measures phase synchronization between signals. It is unclear why Dr. Dempsey has referenced this computation as a measurement of coherence value since it is distinct from coherence value. Phase locking value is a phase interaction which may be calculated from the absolute value of the mean phase difference between two signals expressed as a complex unit-length vector. Phase-locking value is distinct from coherence value measurement.
- 101. Dr. Dempsey also references wavelet coherence and partial coherence. Wavelet coherence can be used to detect common time-localized oscillations in nonstationary signals. Partial coherence measures the linear relationship between two signals after the influence of a third signal has been removed. Both wavelet coherence and partial coherence are derivative of other computations of coherence, meaning the calculations use the same base as magnitude-squared coherence, but take the calculations a step further. Therefore, these calculations are not wholly distinct from magnitude-squared coherence as Dr. Dempsey implies.
- 102. In any case, regardless of whether a POSITA uses magnitude-squared coherence or another simpler method to measure coherence, the methods would not be expected to lead to different results. Similar to the differing uses of inches or centimeters to measure the height of a person, the different methods of measurements of coherence value merely provide different ways of reaching the same results. A person who is 72 inches tall is equivalently 182.88 centimeters. Although using different numbers to refer to the same height may be confusing to some, the

different units of measurement provide the same result – the person has a specific height that is the same height whether measured in inches, centimeters, feet, meters, or any other valid unit of measurement (and it should be clear that a treatment that might increase a person's height, would do so whether the result is measured in inches or in centimeters). Similarly, the resulting measurements for coherence would show the degree or measure of similarity between two waveforms, even if technically different measurements.

- Dr. Dempsey fails to understand that there are multiple methods of measuring a coherence value and that the different methods would not be expected to provide different results. As a result of this misunderstanding as to the multiple methods of measuring coherence value, the underlying premise of Dr. Dempsey's argument as to the meaning of coherence value is flawed. Just like the case with inches and centimeters, the actual number might be different, but the result (e.g., how tall a person is) does not change. That is, a coherence value may be measured using different methods, but the different methods would not be expected to provide different conclusions based on the coherence value.
- Lastly, Defendant proposes an alternative construction for "coherence value": "The difference between the frequency and phase of two waves." This construction is not consistent with the usage of "coherence value" in the claims, the specification, or the prosecution history, as discussed *supra*. Furthermore, this alternative construction is not consistent with the plain and ordinary meaning of "coherence value." Most egregiously, Defendant has imported "phase" into the meaning of "coherence value" even though the claims, specification, and prosecution history clearly use the term with reference to intrinsic frequencies, not phase.
- Furthermore, Defendant argues that this alternative construction for "coherence value" is consistent with statements in the prosecution history. See Defendant's Opening Claim Construction Brief, p. 14-15. However, Defendant fails to explain how the cited statement from the prosecution history (i.e. "Coherence is defined as waves with the same frequency and in phase") supports its proposed construction. *Id.* From my review of the prosecution histories, the cited language is the Examiner's summary of how coherence is used in a prior art reference

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(Katz). See Dkt. 029-07, '408 Patent Prosecution History at *658.

- In contrast, Wave explicitly explained what it meant by "coherence value" in its patents during the prosecution of the '408 Patent. See supra '408 Prosecution History at *738. ("The Examiner refers to a definition of "coherence" in the Office Action based on Katz. However, Applicants respectfully disagree with this characterization of the term based on the way the term is used in the claims and specification herein.) Therefore, the Examiner proposed a definition for coherence and Wave disagreed with the definition. Because the Examiner allowed the application without re-asserting the disputed definition, the Examiner understood coherence to be defined as Applicant defined it.
- 107. In summary, it is my opinion that a POSITA would understand the meaning of "coherence value" to be the plain and ordinary meaning, namely a measure of similarity between two or more signals over time, as proposed by Wave. Furthermore, a POSITA would understand the meaning of the term and the scope of the claims in which it appears with reasonable certainty.

"MOVE AN/THE [INTRINSIC FREQUENCY... Q-FACTOR...]; MOVING, XI. USING THE MAGNETIC FIELD...[AN INTRINSIC FREQUENCY,...Q-FACTOR...]"

I understand that the Defendant disagrees with Wave about the proper construction of the phrase "Move/an/the [intrinsic frequency...Q-factor...]" as that phrase appears in Claims 1 and 12 of the '408 Patent and Claim 1 of the '490 Patent. I understand that the Defendant also disagrees with Wave about the proper construction of the phrase "Moving, using the magnetic field,....[an intrinsic frequency,...Q-factor...]" as that phrase appears in Claims 1-2 of the '737 Patent. The Parties' proposed constructions are set forth in the chart below.

Claim Term/Phrase	Plaintiff's Construction	Defendant's Construction
Move/an/the [intrinsic frequencyQ-factor]	Not indefinite or invalid.	Indefinite & Invalid: Not enabled/lacking written description/failure of best mode.
'408 Patent, Claims 1, 12 '490 Patent, Claim 1		

Moving, using the magnetic field,[an intrinsic frequency,Q-factor]	
'737 Patent, Claims 1-2	

109. The intrinsic evidence (claims, specifications, and prosecution histories) establishes that a POSITA would understand the meaning of the phrase "Move/an/the [intrinsic frequency...Q-factor...]" and the claims in which it appears with reasonable certainty. The intrinsic evidence also clearly establishes that a POSITA would know how to move the alternative limitations (intrinsic frequency, Q-factor, coherence value, and EEG phase) and to what degree such alternative limitations should be moved to practice the claimed invention.

110. For example, Claim 1 of the '408 Patent recites in part:

move an intrinsic frequency of a specified EEG band of the subject toward a target intrinsic frequency of the specified EEG band using the magnetic field, move a Q-factor of the intrinsic frequency toward a target Q-factor of the intrinsic frequency using the magnetic field,

move a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value using the magnetic field wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to the head of the subject; and

move an EEG phase between two sites in the brain of a subject of a specified EEG frequency toward a target EEG phase of the specified EEG frequency using the magnetic field wherein the magnetic field comprises one or more magnetic field generators that are of the same frequency and are in-phase with each other, of the same frequency and out of phase with each other, or a combination thereof... (emphasis added).

Similarly, Claim 12 of the '408 Patent recites in part: 111.

moves at least one of:

- (a) an intrinsic frequency of a brain of the subject in a specified EEG band to a target intrinsic frequency within the specified EEG band using the magnetic
- (b) a O-factor of an intrinsic frequency of the brain of the subject within a specified EEG band to a target Q-factor of the intrinsic frequency using the magnetic field;

- (c) a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band using the magnetic field wherein if the coherence value is higher than a pre-selected coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the pre-selected coherence value, applying at least one synchronized magnetic field close to the head of the subject; and (d) an EEG phase between two sites in the brain of the subject of a specified EEG frequency using the magnetic field wherein the magnetic field comprises a first magnetic field that is in-phase with a second magnetic field or a first magnetic field that is out of phase with a second magnetic field. (emphasis added).
- 112. It is my opinion that a POSITA, in light of the disclosure in the specification, would understand how to use magnetic field parameters to move the alternative limitations (intrinsic frequency, Q-factor, coherence value, and EEG phase) as recited in Claims 1 and 12 of the '408 Patent.
 - 113. Claim 1 of the '490 Patent recites in part:
 - b) a processor configured to control the magnetic field based on said subject data value, wherein the magnetic field is configured to
 - i) move the first intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using said magnetic field,
 - ii) move the O-factor of the first intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using the magnetic field,
 - iii) move the coherence value by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to the head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value, or
 - iv) move the EEG phase of the specified EEG frequency, wherein the magnetic field comprises a first magnetic field that is in-phase with the second magnetic field or a first magnetic field that is out of phase with the second magnetic field...(emphasis added)

It is my opinion that a POSITA would understand how to use magnetic field parameters to move the alternative limitations (intrinsic frequency, Q-factor, coherence value, and EEG phase) as recited in Claim 1 of the '490 Patent.

Claim 1 of the '737 Patent recites in part:

A method comprising:

- (a) adjusting output of a magnetic field;
- (b) applying said magnetic field close to a head of a subject; and
- (c) moving, using the magnetic field, at least one of

an intrinsic frequency of a specified EEG band of the subject toward a preselected intrinsic frequency of the specified EEG band and a **Q-factor** of an intrinsic frequency within a specified EEG band of the subject toward a pre-selected Q-factor...(emphasis added).

It is my opinion that a POSITA would understand how to use magnetic field parameters to move the alternative limitations (intrinsic frequency, Q-factor) as recited in Claim 1 of the '737 Patent.

Claim 2 of the '737 Patent recites in part: 115.

A method comprising:

- (a) adjusting output of a magnetic field;
- (b) applying said magnetic field close to a head of a subject; and
- (c) moving, using the magnetic field, an intrinsic frequency of a specified EEG band of the subject toward a pre-selected intrinsic frequency of the specified EEG band, (emphasis added).

It is my opinion that a POSITA would understand how to use magnetic field parameters to move the intrinsic frequency, as recited in Claim 1 of the '737 Patent.

116. The specification of the '408 Patent also provides numerous examples that would inform a POSITA how to use magnetic field parameters to move an intrinsic frequency. The '408 Patent discloses:

In another aspect are methods of altering an intrinsic frequency of a brain of a subject within a specified EEG band, comprising: (a) determining the intrinsic frequency of the subject within the specified EEG band; (b) comparing the intrinsic frequency from step (a) to an average intrinsic frequency of a control group; (c) if the intrinsic frequency from step (a) is higher than the average intrinsic frequency of the control group, shifting down the intrinsic frequency of the subject by applying a specific magnetic field close to a head of the subject, wherein said specific magnetic field has a frequency lower than the intrinsic frequency of the subject; and (d) if the intrinsic frequency from step (a) is lower than the average intrinsic frequency of the control group, shifting up the intrinsic frequency of the subject by applying a specific magnetic field close to a head of the subject, wherein said specific magnetic field has a frequency higher than the intrinsic frequency of the subject. In some embodiments, the control group is a set of subjects having a particular trait, characteristic, ability, or feature. In some embodiments, the control group is a control group set of subjects not having a neurological disorder disclosed herein (e.g., Post Traumatic Stress Disorder, coma, amblyopia or Parkinson's disease). '408 Patent 1:46-67. See also '408 Patent 17:39-55 (similar); '737 Patent 6:4-22 (similar); '737 Patent 23:7-24; '737 Patent 24:4-21; '490 Patent 6:8-25 (similar); '490 Patent 31:4-22. (emphasis added).

117. This disclosure from the '408 Patent (which is similarly disclosed in the '737 Patent and the '490 Patent) illustrates how an intrinsic frequency can be moved. To shift down the intrinsic frequency, a specific magnetic field can be applied in which the specific magnetic

field has a frequency *lower than* the intrinsic frequency of the subject. To shift up the intrinsic frequency, a specific magnetic field can be applied in which the specific magnetic field has a frequency higher than the intrinsic frequency of the subject. A POSITA, upon being informed of this guidance in the '408 Patent, would understand how to move an intrinsic frequency (i.e., by applying specific magnetic fields having frequencies that are lower than or higher than the intrinsic frequency of the subject).

The foregoing disclosure from the '408 Patent is not an isolated disclosure. The 118. '408 Patent includes additional examples illustrating how an intrinsic frequency can be moved. The '408 Patent further discloses:

Disclosed herein, in certain embodiments, are methods of treating PTSD by altering an intrinsic frequency of a brain of a subject within a specified EEG band, comprising: (a) determining the intrinsic frequency of the subject within the specified EEG band; (b) comparing the intrinsic frequency from step (a) to an average intrinsic frequency of a control group; (c) if the intrinsic frequency from step (a) is higher than the average intrinsic frequency of the control group, shifting down the intrinsic frequency of the subject by applying a specific magnetic field close to a head of the subject, wherein said specific magnetic field has a frequency lower than the intrinsic frequency of the subject; and (d) if the intrinsic frequency from step (a) is lower than the average intrinsic frequency of the control group, shifting up the intrinsic frequency of the subject by applying a specific magnetic field close to a head of the subject, wherein said specific magnetic field has a frequency higher than the intrinsic frequency of the subject. '408 Patent 19:27-44. See also '408 Patent 21:16-60 (similar disclosure for treatment of coma); '408 Patent 24:12-61 (similar disclosure for treatment of Parkinson's Disease). (emphasis added).

119. Another example provided in the specification of the '408 Patent (and similarly in the '737 Patent and the '490 Patent) details how the intrinsic frequency can be moved. The '408 Patent discloses:

Provided herein is a method of altering an intrinsic frequency of a brain of a subject within a specified EEG band, comprising determining the intrinsic frequency of the subject within the specified EEG band; comparing the intrinsic frequency from step (a) to an average intrinsic frequency of a control group; if the intrinsic frequency from step (a) is higher than the average intrinsic frequency of the control group, shifting down the intrinsic frequency of the subject by applying a specific magnetic field close to a head of the subject, wherein said specific magnetic field has a frequency lower than the intrinsic frequency of the subject; and if the intrinsic frequency from step (a) is lower than the average intrinsic frequency of the control group, shifting up the intrinsic frequency of the subject by applying a specific magnetic field close to a head of the subject, wherein said specific magnetic field has a frequency higher than the intrinsic frequency of the subject. In some

embodiments, a NEST device, such as one of the NEST devices (pMERT devices) described herein is used to create the magnetic field of the method. '408 Patent 40:64-41:15; '490 Patent 58:16-35 (similar); '737 Patent 53:6-26. (emphasis added).

- 120. Therefore, there are multiple passages in the '408 Patent that detail how an intrinsic frequency can be moved. The '490 Patent and the '737 Patent similarly disclose multiple passages detailing how an intrinsic frequency can be moved as evidenced by the additional citations provided. Thus, there are finite solutions involved in moving an intrinsic frequency and a POSITA would know which of these finite solutions would be used in moving the intrinsic frequency in light of the claim language and specification.
- 121. In addition, the '408 Patent recites disclosures that illustrate how a Q-factor can be moved. The '408 Patent discloses:

Disclosed herein, in certain embodiments, are methods of treating PTSD by modulating the electrical activity of a brain in a subject in need thereof, comprising: (a) adjusting output of a magnetic field for influencing a Q-factor (i.e., a measure of frequency selectivity of a specified EEG band) of the subject toward a target Q-factor of the band; and (b) applying said magnetic field close to a head of the subject. In some embodiments, the Q-factor is adjusted (or tuned) up. In another aspect are methods of modulating the electrical activity of a brain in a subject in need thereof, comprising: determining the Q-factor of the intrinsic frequency within the specified EEG band of the subject; comparing the Q-factor of the intrinsic frequency from step (a) to an average Qfactor of the intrinsic frequency of a control group; if the Q-factor of the intrinsic frequency from step (a) is higher than the average Q-factor of the intrinsic frequency of the control group, tuning down the O-factor of the intrinsic frequency of the subject by applying a magnetic field with a plurality of frequencies or with a single target frequency close to a head of the subject; and if the Q-factor of the intrinsic frequency from step (a) is lower than the average Q-factor of the intrinsic frequency of the control group, tuning up the Q-factor of the intrinsic frequency of the subject by applying a magnetic field with a target frequency to a head of the subject. '408 Patent 19:44-67. See also '408 Patent 21:16-60 (similar disclosure for treatment of coma); '408 Patent 24:12-61 (similar disclosure for treatment of Parkinson's Disease). (emphasis added).

122. This disclosure from the '408 Patent provides an example of how the Q factor can be moved. To tune down the Q factor, a magnetic field can be applied in which the magnetic field has a plurality of frequencies or a single target frequency. To tune up the Q factor, a magnetic field can be applied in which the magnetic field has a target frequency. A POSITA would understand how to tune down or tune up a O-factor in light of this disclosure from the

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123. The '408 Patent (and similarly the '737 Patent and the '490 Patent) provides additional examples of how the Q factor can be moved. For example, the '408 Patent discloses:

Provided herein is a method of altering a **Q-factor** of an intrinsic frequency within a specified EEG band of a subject, comprising determining the Q-factor of the intrinsic frequency within the specified EEG band of the subject; comparing the Q-factor of the intrinsic frequency from step (a) to an average Q-factor of the intrinsic frequency of a control group; if the Q-factor of the intrinsic frequency from step (a) is higher than the average Q-factor of the intrinsic frequency of the control group, tuning down the Q-factor of the intrinsic frequency of the subject by applying a magnetic field with varying frequencies close to a head of the subject; and if the Q-factor of the intrinsic frequency from step (a) is lower than the average Q-factor of the intrinsic frequency of the control group, tuning up the **Q-factor** of the intrinsic frequency of the subject by applying a specific magnetic field with a target frequency close to a head of the subject. In some embodiments, a NEST device, such as one of the NEST devices (pMERT devices) described herein is used to create the magnetic field of the method. '408 Patent 41:16-34. See also '737 Patent 53:27-46 (similar); '490 Patent 58:36-55 (similar). (emphasis added).

- 124. Therefore, there are similarly finite solutions involved in moving a Q-factor and a POSITA would know which of these finite solutions would be used in moving the Q-factor in light of the claim language and specification.
- 125. The '408 Patent similarly informs a POSITA about how to move a coherence value. Claim 1 of the '408 Patent recites in part:

move a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value using the magnetic field wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to the head of the subject... (emphasis added).

126. Claim 12 of the '408 Patent similarly recites in part:

moves...a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band using the magnetic field wherein if the coherence value is higher than a pre-selected coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the pre-selected coherence value, applying at least one synchronized magnetic field close to the head of the subject. (emphasis added).

- 127. Claim 1 of the '490 Patent recites in part:
- iii) move the coherence value by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to the head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value... (emphasis added).
- Patent and Claim 1 from the '490 Patent, in light of the respective specification, would equally understand how to move a coherence value. When the coherence value is to be lowered (i.e., if the coherence value is higher than a pre-selected coherence value), at least two asynchronous magnetic fields are to be applied. When the coherence value is to be raised (i.e., if the coherence value is lower than the pre-selected coherence value), at least one synchronized magnetic field is to be applied. There are finite solutions to achieve the outcome of moving the coherence value and a POSITA would understand how to move the coherence value based on these finite solutions.
- 129. Finally, the '408 Patent also informs a POSITA about how to move an EEG phase. Claim 1 of the '408 Patent discloses in part:
 - **move an EEG phase** between two sites in the brain of a subject of a specified EEG frequency toward a target EEG phase of the specified EEG frequency using the magnetic field wherein the magnetic field comprises one or more magnetic field generators that are of the same frequency and are **in-phase** with each other, of the same frequency and **out of phase** with each other, or a combination thereof.... (emphasis added).
 - 130. Claim 12 of the '408 Patent discloses in part:
 - move ... an EEG phase between two sites in the brain of the subject of a specified EEG frequency using the magnetic field wherein the magnetic field comprises a first magnetic field that is **in-phase** with a second magnetic field or a first magnetic field that is **out of phase** with a second magnetic field. (emphasis added).
 - 131. Claim 1 of the '490 Patent discloses in part: "iv) move the EEG phase of the

specified EEG frequency, wherein the magnetic field comprises a first magnetic field that is inphase with the second magnetic field or a first magnetic field that is out of phase with the second magnetic field..." (emphasis added).

- 132. A POSITA, when viewing this claim language from Claims 1 and 12 of the '408 Patent and Claim 1 of the '490 Patent, in light of the respective specifications, would understand that the EEG phase can be moved by using magnetic fields that are in-phase or out of phase. For example, to move the EEG phase to be in phase, an in-phase magnetic field can be used. To move the EEG phase to be out of phase, an out of phase magnetic field can be applied. There are finite solutions to achieve the outcome of moving the EEG phase and a POSITA would understand how to move the EEG phase based on these finite solutions.
- The Prosecution History for the '408, '490, and '737 Patents further supports that 133. a POSITA would understand how to move the intrinsic frequency, Q-factor, coherence value, and EEG phase. For example, the '737 Prosecution History discloses:

The Examiner suggested "amending the claim to positively recite the item that moves the intrinsic frequency of the EEG band **OR** Q-factor so that it reads -- ... moving, using the magnetic field, ... --". Without conceding the appropriateness of such rejection and in order to advance prosecution, Applicants have made the suggested amendments to claims 1 and 2 and respectfully request that this rejection be withdrawn and the pending claims be advanced to allowance." '737 Prosecution History at *1551. (emphasis added).

This passage from the '737 Prosecution History establishes that the Patent Examiner understood how the magnetic field could be used to move the intrinsic frequency or the Q-factor because the Examiner suggested a proposed change to the claim language.

- Thus, the intrinsic evidence establishes that the magnetic field can be used to shift or alter an intrinsic frequency, a Q-factor, a coherence value, or an EEG phase. The specification also teaches how to shift or alter an intrinsic frequency, a Q-factor, a coherence value, or an EEG phase.
- The '408 Patent, the '490 Patent, and the '737 Patent each refer to 4 parameters 135. that can be used to manipulate the magnetic field.

- Three¹ parameters of magnetic fields generated by the devices described can be manipulated:
- (a) the **intensity of the magnetic field** at the treatment site, which can be determined by the strength of the magnets used and the distance between the magnets and the subject's head;
- (b) the **frequency of the magnetic field**, i.e., the rate of change of the magnetic field, which can be determined by movements of at least one magnet, such as by varying the speed at which at least one magnet moved relative to the application area:
- (c) the amplitude of the net change in magnetic flux (or **waveform**) to which the application area is subjected, and
- (d) the **phase of the magnetic field** between two (or more) magnets (i.e. the magnetic phase) when the magnetic field frequencies of the two (or more) magnets are the same (or substantially the same). '490 Patent, 48:62-49:12; '408 Patent, 31:37-54 (similar); '737 Patent, 43:52-44:2. (emphasis added).
- 136. In addition, the '408 Patent, the '490 Patent, and the '737 Patent each incorporate by reference several articles that further support that a POSITA would understand how to move the alternative limitations (intrinsic frequency, Q-factor, coherence, EEG phase). One of the articles incorporated by reference is Jin Y et al. Therapeutic effects of individualized alpha frequency transcranial magnetic stimulation (alphaTMS) on the negative symptoms of schizophrenia. *Schizophr Bull.* 32(3):556-61 (2006 July; Epub 2005 Oct. 27). This article describes four stimulation parameters that require optimization for rTMS. The four parameters are:
 - (a) Frequency—Higher frequencies (>10 Hz) are believed to increase cortical excitability;
 - (b) Intensity—As a percentage of the threshold at which motor activity can be elicited (~1-2 Tesla);
 - (c) Duration—Pulse trains are brief (1-2 seconds), and intertrain intervals can be 30-60 seconds; and
 - (d) Site of Stimulation—Depending on patient population or specific brain functions. '408 Patent, 46:18-25.
- 137. The specification for the '408 Patent, the '490 Patent, and the '737 Patent also reference four parameters that can be manipulated to control the magnetic field as discussed *infra*

¹ Even though "three" parameters are referenced, there are in fact four parameters that are disclosed.

in Section XII which further establishes that a POSITA would know how to move the alternative limitations (intrinsic frequency, Q-factor, coherence value, and EEG phase). Even though that section specifically refers to the '490 Patent, the argument similarly applies to the '408 Patent and the '737 Patent, which both disclose that the same four parameters that can be manipulated.

- Therefore, based on the guidance available in the specification as well as the 138. knowledge available in the art, a POSITA would understand how to manipulate a magnetic field to move an intrinsic frequency, Q-factor, coherence value, or EEG phase as described in the claims.
- In addition, a POSITA would understand the degree to which the alternative limitations are to be moved. The intrinsic evidence, as exemplified by the claim language, clearly establishes the boundaries of the movement.
 - 140. For example, Claim 1 of the '408 Patent recites in part:

A method of treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive performance, in a subject, comprising: (a) adjusting a setting of a magnetic field such that the magnetic field is configured to do one or more of the following:

move an intrinsic frequency of a specified EEG band of the subject toward a target intrinsic frequency of the specified EEG band using the magnetic field, (emphasis added).

According to this claim, the movement is "toward a target intrinsic frequency." Therefore, as a POSITA, I understand that there is a clear boundary involved in moving the intrinsic frequency for this particular claim.

141. Claim 12 of the '408 Patent recites in part:

A device for use in treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive performance in a subject, comprising: a means for applying a magnetic field to a head of a subject; whereby the means for applying the magnetic field comprises: a first processor that controls the application of the magnetic field and wherein the first processor or a second processor moves at least one of: an intrinsic frequency of a brain of the subject in a specified EEG band to a target intrinsic frequency within the specified EEG band using the magnetic field; (emphasis added).

According to this claim, the movement is "toward a target intrinsic frequency." Therefore, as a POSITA, I also understand that there is a clear boundary involved in moving the intrinsic frequency for this particular claim.

- 142. Claim 1 of the '490 Patent recites in part:
- b) a processor configured to control the magnetic field based on said subject data value, wherein the magnetic field is configured to
- i) move the first intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using said magnetic field... (emphasis added).

According to this claim, the movement is "in a pre-selected direction, up or down." Therefore, as a POSITA, I similarly understand that there is a clear boundary involved in moving the intrinsic frequency for this particular claim.

- 143. Claim 1 of the '737 Patent recites in part
- 1. A method comprising:
- (a) adjusting output of a magnetic field;
- (b) applying said magnetic field close to a head of a subject; and
- (c) moving, using the magnetic field, at least one of
- an intrinsic frequency of a specified EEG band of the subject toward a preselected intrinsic frequency of the specified EEG band and
- a Q-factor of an intrinsic frequency within a specified EEG band of the subject toward a pre-selected Q-factor,

wherein the pre-selected intrinsic frequency is a frequency that increases blood flow in the cortex of the subject, and wherein the pre-selected Q-factor is a Q-factor that increases blood flow in the cortex of the subject. (emphasis added).

According to this claim, the movement is "toward a preselected intrinsic frequency." Therefore, as a POSITA, I understand that there is a clear boundary involved in moving the intrinsic frequency for this particular claim.

144. Claim 2 of the '737 Patent recites in part

A method comprising:

- (a) adjusting output of a magnetic field;
- (b) applying said magnetic field close to a head of a subject; and
- (c) moving, using the magnetic field, an intrinsic frequency of a specified EEG band of the subject **toward a pre-selected intrinsic frequency** of the specified EEG band,

wherein the pre-selected intrinsic frequency is a frequency that decreases blood flow in a lower region of the brain of the subject. (emphasis added).

According to this claim, the movement is "toward a pre-selected intrinsic frequency." Therefore, as a POSITA, I also understand that there is a clear boundary involved in moving the intrinsic frequency for this particular claim.

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- 145. Therefore, the degree of movement is explicitly provided in the claims. A POSITA would understand the degree to which to move the alternative limitations (intrinsic frequency, Q-factor, coherence value, EEG phase) because a POSITA would read the claims in their entirety and would not remove the portions that clearly establish the degree to which the alternative limitations are to be moved.
- 146. Perhaps reflecting his apparent lack of experience with TMS, Dr. Dempsey inaccurately declares that the '408 Patent, the '490 Patent, and the '737 Patent "fail to instruct a POSITA either *how* to move an intrinsic frequency, Q-factor, etc., *or when or to what degree* such an intrinsic frequency, Q-factor, etc., is actually moved." Dkt. 34-1, Dempsey Declaration, p. 7. As established *supra*, a POSITA would clearly understand how to move and to what degree to move the alternative limitations (intrinsic frequency, Q-factor, coherence value, EEG phase). Dr. Dempsey also improperly ignores key claim limitations in deciding that the degree of movement would not be known to a POSITA and thus his analysis is flawed. Moreover, it is unclear what Dr. Dempsey means by "when" because Dr. Dempsey does not elaborate on this assertion.
- 147. Inexplicably, Dr. Dempsey also declares that a person could quite literally infringe Claim 2 of the '737 Patent by taking a magnet and waving it over one's head. A POSITA would not consider "waving" a "magnet" over a head as a conventional form of medicine nor would they conflate that with TMS. It is my understanding that it is improper for Dr. Dempsey to provide any opinion as to the issue of infringement as that is the sole provenance of the trier of fact. However, since he has rendered such an opinion, I will address this issue here. Dr. Dempsey's opinion intentionally ignores the actual claim language and all of the claim elements contained therein, and instead intentionally references words in a single claim element and adopting a superficial description of how magnets operate. When viewed in its entirety,

Claim 2 of the '737 Patent contains a number of claim elements that are not considered or incorporated into Dr. Dempsey's opinion as to infringement. Similarly, his opinion is based on a simplified and rudimentary understanding of magnets, inconsistent with the actual language of Claim 2 of the '737 Patent. As such, I disagree with Dr. Dempsey's underlying approach and his ultimate stated opinion as to the application of Claim 2 of the '737 Patent relative to someone waving a magnet over their head.

- In summary, it is my opinion that a POSITA would understand the meaning of the phrase and the scope of the claims in which it appears with reasonable certainty, as Wave has established, because a POSITA would clearly understand how to move an intrinsic frequency, Qfactor, coherence value, or EEG phase and would understand the degree of movement.
- 149. Furthermore, the above analysis also applies to the other claim phrase ("moving, using the magnetic field...[an intrinsic frequency,...Q factor...]" for the reasons provided with respect to the '737 Patent in this Section. The language for this other claim phrase is simply reversed and has a similar meaning.

"CONTROL THE MAGNETIC FIELD" XII.

I understand that the Defendant disagrees with Wave about the proper construction of the phrase "control the magnetic field" as that phrase appears in Claim 1 of the '490 Patent. The Parties' proposed constructions are set forth in the chart below.

Claim Term/Phrase	Plaintiff's Construction	Defendant's Construction
Control the magnetic field	Not indefinite or invalid.	Indefinite & Invalid: Not
Control the magnetic field		enabled/lacking written
'490 Patent, Claim 1		description/failure of best mode.

- A POSITA would understand the metes and bounds of the phrase "control the magnetic field" based on the intrinsic evidence (claims, specification, prosecution history) with reasonable certainty.
 - 152. Claim 1 of the '490 Patent discloses in part:
 - b) a processor configured to control the magnetic field based on said subject data value, wherein the magnetic field is configured to

- i) move the first intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using said magnetic field,
- ii) **move the Q-factor** of the first intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using the magnetic field,
- iii) **move the coherence value** by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to the head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value, or
- iv) **move the EEG phase** of the specified EEG frequency, wherein the magnetic field comprises a first magnetic field that is in-phase with the second magnetic field or a first magnetic field that is out of phase with the second magnetic field...(emphasis added).
- 153. It is my opinion that a POSITA, upon viewing this claim in light of the specification, would understand how to control the magnetic field to move each of the alternative limitations (e.g., first intrinsic frequency, Q-factor, coherence value, and EEG phase). An explanation for why moving each of the alternative limitations would be understood by a POSITA with reasonable certainty is provided *supra* in section XI.
- 154. The specification of the '490 Patent provides multiple examples that illustrate how to control the magnetic field. The '490 Patent discloses:
 - Three² parameters of magnetic fields generated by the devices described can be manipulated:
 - (a) the **intensity of the magnetic field** at the treatment site, which can be determined by the strength of the magnets used and the distance between the magnets and the subject's head;
 - (b) the **frequency of the magnetic field**, i.e., the rate of change of the magnetic field, which can be determined by movements of at least one magnet, such as by varying the speed at which at least one magnet moved relative to the application area:
 - (c) the amplitude of the net change in magnetic flux (or **waveform**) to which the application area is subjected, and
 - (d) the **phase of the magnetic field** between two (or more) magnets (i.e. the magnetic phase) when the magnetic field frequencies of the two (or more) magnets are the same (or substantially the same). '490 Patent, 48:62-49:12. (emphasis added).

² Even though "three" parameters are referenced, there are in fact four parameters that are disclosed.

magnets used and the distance between the magnets and the subject's head."

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- The specification of the '490 Patent provides numerous examples of how the 155. intensity of the magnetic field can be determined. According to the passage provided above, the intensity of the magnetic field at the treatment site "can be determined by the strength of the
- 156. In addition, specific numbers are provided for the intensity of the magnetic field. For example, when referring to a specific device, the '490 Patent discloses: "the pMERT (permanent Magneto-EEG Resonant Therapy) device (i.e. the NEST device) comprises one or more powerful magnets (>5000 G each) that rotate at a specific frequency or frequencies to bring about the desired therapy." '490 Patent, 45:65-46:2. (emphasis added).
- 157. Furthermore, a range for the strength of the magnets is provided. The '490 Patent discloses:

While permanent magnets of any strength may be utilized for the methods and devices described herein, generally magnets having strengths within the range of about 10 Gauss to about 4 Tesla can be used. In some embodiments, the strength of at least one permanent magnet is from about 100 Gauss to about 2 Tesla. In some embodiments, the strength of at least one permanent magnet is from about **300 Gauss to about 1 Tesla**. '490 Patent, 48:25-32. (emphasis added).

158. Even though the strengths of the magnets are described in terms of permanent magnets, a POSITA would be able to determine the strength of the magnetic field because examples of the distances between the permanent magnets and the subject are provided. The '490 Patent discloses:

In some embodiments, the distance between the at least one permanent magnet and the subject is from about 0 inches to about 12 inches, from about 1/32 inches to about 12 inches, from about 1/16 inches to about 5 inches, or from about 1 inch to about 5 inches. As used herein, the term "about" when referring to distance between the at least one permanent magnet and the subject can mean variations of 1/64 inch, 1/32 inch, 1/16 inch, ½ inch, ¼ inch, ¼ inch, ½ inch, or 1 inch. '490 Patent, 9:59-67.

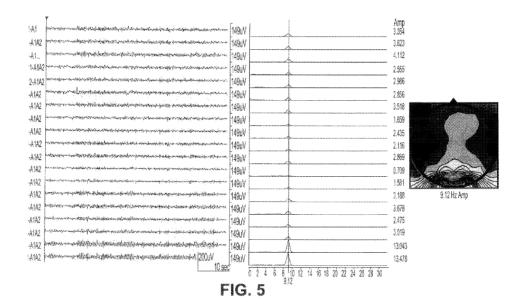
159. Therefore, according to the specification, (a) the intensity of the magnetic field at the treatment site can be determined by the strength of the magnets used and the distance between the magnets and the subject's head ('490 Patent, 48:64-67), (b) the strength of the

magnets is provided, and (c) the distance from the subject's head is provided. By varying the intensity of the magnet and the distance to the subject's head, the intensity of the magnetic field can be controlled.

- 160. Therefore, a POSITA would be able to control the magnetic field by determining the intensity of the magnetic field because there are finite solutions that would be guided by the intrinsic evidence.
- 161. The frequency of the magnetic field can also be controlled. The '490 Patent discloses in relation to the manipulation of frequency: "the **frequency of the magnetic field**, i.e., the rate of change of the magnetic field, which can be determined by movements of at least one magnet, such as by varying the speed at which at least one magnet moved relative to the application area." '490 Patent, 49:1-5. (emphasis added).
- 162. Some of the examples of the frequency provide specific quantities. The '490 Patent discloses: "In some embodiments, the device comprises logic that controls the frequency in increments of about 0.1 Hz." '490 Patent, 5:24-25; see also '490 Patent, 30:21-22. (emphasis added). The '490 Patent further discloses:

In some embodiments of at least one aspect described above, the devices further comprise logic that controls the frequency to be any frequency **between about 2 and about 20 Hz in increments of about 0.1 Hz**. In some embodiments of at least one aspect described above, the devices further comprise logic that controls the frequency to be any frequency between about 2 and about 50 Hz in increments of about 0.1 Hz." '490 Patent, 11:59-65. (emphasis added).

- FIG. 5 of the '490 Patent also illustrates an exemplary frequency (e.g., 9.12 Hz). 163.
- Therefore, the specification of the '490 Patent provides a specific range of 164.



frequencies and specific examples of frequencies. A POSITA who is informed by the claims and the specification would understand which frequencies are available for use because there are finite solutions that would be guided by the intrinsic evidence.

The '490 Patent further discloses in relation to the waveform of the magnetic 165. field:

In some embodiments, the frequency of the output current has a waveform. In some embodiments, the waveform is a sinusoidal or near-sinusoidal AC microcurrent waveform (i.e. a controlled waveform). In some embodiments, the waveform is any waveform described herein, including but not limited to a half waveform and/or a full waveform." '490 Patent, 65:53-58. (emphasis added).

Therefore, a POSITA who is informed by the claim language and the specification would understand the waveforms that can be used. The specification provides specific examples, and a POSITA, can extrapolate from these examples without difficulty and without any undue experimentation, which waveforms are best suited to treat each subject.

166. The '490 Patent further discloses in relation to the phase of the magnetic field:

Even a device having a magnetic phase of 0, where the magnets spin at the same

frequencies, and in-phase relative to the treatment surface of the device (and/or relative to the head of the subject), may influence the EEG phase between two locations measured on the subject's head. For example, if prior to treatment, two EEG electrodes take EEG readings within an EEG band, and the frequencies are the same (or substantially so), however, the EEG readings have peaks for each electrode at different times (i.e. a non-zero EEG phase), a device as described herein may influence the EEG phase by applying a magnetic field having a magnetic phase (i.e. where the magnets move at the same frequency and in-phase with each other). '490 Patent, 55:24-36.

- The '490 Patent specifically describes a magnetic phase of 0 and its usage in 167. influencing the EEG phase between two locations measured on the subject's head. Therefore, a specific example of magnetic phase provides explicit guidance for a POSITA.
- The specification of the '490 Patent describes four parameters of magnetic fields 168. that can be manipulated: (1) intensity, (2) frequency, (3) waveform, and (4) phase. The specification also describes different quantities for intensity, frequency, and phase. The specification further describes different types of waveforms. Therefore, a parameter space is provided that would allow a POSITA to identify the parameters of the magnetic field to effectuate the limitation (e.g., moving a first intrinsic frequency, Q-factor, coherence value, and EEG phase).
 - Dr. Dempsey asserts in relation to this claim phrase: 169.

However, the patent does not teach how to use or control movement of an intrinsic frequency, Q-factor, coherence value, or EEG phase to achieve these objectives. Thus a POSITA would not be reasonably informed as to how to control or adjust the magnetic field to achieve the desired result. Dkt. 34-1, Dempsey Declaration, p. 9.

As explained supra in Section XI, the intrinsic evidence provides plenty of support to inform a POSITA about how to move an intrinsic frequency, Q-factor, coherence value, or EEG phase.

170. Dr. Dempsey further asserts:

First, experimentation would be required to determine how to reliably affect movement of intrinsic frequency, q-factor, and coherence value for a given patient. Further, the effects of such movement would likely vary by frequency, band, lead location, magnet placement relative to the head, and a myriad of other factors that could be adjusted. It also may vary based on the specific patient being treated. Dkt. 34-1, Dempsey Declaration, p. 9. (emphasis added).

This criticism by Dr. Dempsey fails to support Defendant's position because Dr. Dempsey has not established that the degree of experimentation is too large to practice the claim. As set forth *supra* in this Section, many of the parameters that Dr. Dempsey references (frequency, band, magnet placement relative to the head) are explicitly mentioned in the specifications for the '490 Patent. The specification for the '490 Patent also references another parameter that Dr. Dempsey references – different types of lead location. *See e.g.*, '490 Patent, 69:13-15 ("Nineteen EEG electrodes (Ag—Ag Cl) are used according to the International 10-20 system and referenced to linked mastoids.").

- 171. I have been informed by counsel that a degree of experimentation is permissible as long as the degree of experimentation is not undue. I have also been informed by counsel that experimentation may be permissible if merely routine or if the specification in question provides a reasonable amount of guidance. For these patents, the experimentation done by a POSITA would be routine and not undue. The specification also provides a reasonable amount of guidance for a POSITA to practice the claim. For example, a POSITA would understand how to determine the desired settings (e.g., frequency, band, lead location, magnet placement relative to the head) to obtain the result described.
- 172. Dr. Dempsey also argues that "significant experimentation would have been required to determine the effect of increasing versus decreasing the intrinsic frequency on blood flow in a cortex or a "lower region of the brain." Dkt. 34-1, Dempsey Declaration, p. 9. This argument is addressed *infra* in Section XIII. Nevertheless, I have been told that the standard is "undue" not "significant" experimentation. In any case, I did not see any analysis from Dr. Dempsey as to why such experimentation would be either "significant" or "undue". For the reasons set out through this and the prior section, any experimentation, in my opinion, would not be "significant" or "undue".
- 173. Dr. Dempsey further references a "prescribed treatment" from the '490 Patent but concludes that "it provides no specifics as to what that might be, or how the desired objectives might be achieved." Dkt. 34-1, Dempsey Declaration, p. 9. As explained supra in Section XII,

the 4 referenced magnetic parameters (intensity, frequency, waveform, phase) may be used to effectuate a desired treatment. Therefore, specifics are adequately disclosed in the subject patents and potential desired objectives (e.g., moving toward a target intrinsic frequency, or the like) are also provided, such that no basis exists for Dr. Dempsey's argument that significant experimentation would have been required to determine the effect of increasing versus decreasing the intrinsic frequency on blood flow in a cortex or a "lower region of the brain." A POSITA would understand that the "prescribed treatment" mentioned in an example of the '490 Patent would consist of the treatment protocol for the patient to move the patient's intrinsic frequency, Q-factor, coherence value, or EEG phase towards the goal or target intrinsic frequency, Q-factor, coherence value, or EEG phase using the magnetic field and manipulating the magnetic field using the four parameters.

- 174. Dr. Dempsey also references a biological feedback sensor from the '490 Patent but argues that the '490 Patent does not teach how it might be used to achieve results. Dr. Dempsey concludes that a "POSITA would be forced to experiment with the many available parameters until the desired changes are detected by the feedback sensor." Dkt. 34-1, Dempsey Declaration, p. 10. A POSITA would know how to make and configure a bio-feedback sensor to detect specific biological parameters. In addition, although a bio-feedback sensor can be used in combination with treatment, the bio-feedback sensor does not appear in the claims, and a POSITA would understand that there are various ways of effectuating treatment without using a bio-feedback sensor. It is my understanding that the scope of the claims determine the invention, not isolated portions of the specification.
- It is therefore my opinion that a POSITA would understand the meaning of the phrase and the scope of the claims in which it appears with reasonable certainty. In addition, it is my opinion that a POSITA would understand how to practice the claim without the need for undue experimentation.
- "A FREQUENCY THAT DECREASES BLOOD FLOW IN A LOWER REGION XIII. OF THE BRAIN OF THE SUBJECT; THE MAGNETIC FIELD...DECREASES THE

BLOOD FLOW OF A LOWER REGION OF THE BRAIN"

I understand that the Defendant disagrees with Wave about the proper construction of the phrase "a frequency that decreases blood flow in a lower region of the brain of the subject" as that phrase appears in Claim 2 of the '737 Patent. I also understand that the Defendant disagrees with Wave about the proper construction of the phrase "the magnetic field...decreases the blood flow of a lower region of the brain" as that phrase appears in Claim 1 of the '490 Patent. The Parties' proposed constructions are set forth in the chart below.

Claim Term/Phrase	Plaintiff's Construction	Defendant's Construction
A frequency that decreases blood flow in a lower region of the brain of the subject	Not indefinite or invalid.	Indefinite & Invalid: Not enabled/lacking written description/failure of best mode.
'737 Patent, Claim 2		
The magnetic fielddecreases the blood flow of a lower region of the brain		
'490 Patent, Claim 1		

- A POSITA would understand the claim phrases as Wave has proposed. That is, a POSITA would understand these two claim phrases with reasonable certainty in light of the intrinsic evidence (claim language, the specification, and the prosecution history).
- Per my review, Dr. Dempsey's and Defendant's concerns and arguments appear 178. to be limited to two aspects of the above claims: (1) the decreased blood flow and (2) the identification of the lower region of the brain.
- 179. The specification for the '737 and '490 Patents establishes a connection between neuronal activity and blood flow. The patents disclose: "Increased neuronal activity in a region of the brain is associated with an increase in blood flow". '737 Patent 30:62-63; '490 Patent, 32:23-24.
 - Furthermore, the patents explain that a pre-selected frequency is a frequency that 180.

decreases blood flow in a lower region of the brain of the subject. The '737 Patent provides support for this claim limitation as follows:

The regional Cerebral Blood Flow (rCBF) of subjects enrolled at the US study site was evaluated using a SPECT scan at baseline and again after the 4 weeks of treatment. A significant correlation between changes in rCBF and HAMD-17 score was found, specifically in the orbital frontal cortex (r=-0.67, P=0.04), prefrontal tip (r=-0.66, P=0.05), and dorsal lateral prefrontal cortex (r=-0.55, P=0.12). See Table 5 showing the correlation between Changes in rCBF (%) and HAMD Score (%). Areas of increased activation of the active NEST device compared to sham were observed, along with areas of deactivation of the active NEST device compared to SHAM. Areas of the cortex were observed to be activated by NEST device treatment compared to SHAM. Areas of the cortex were observed to be deactivated by NEST device compared to SHAM. A significant portion of the cortex was shown to have increased blood flow for the active subjects (using the NEST device) compared to sham. Much of this activation occurs in the prefrontal cortex. Using the therapy, activation of the cortex occurs, especially in the frontal region, whereas deactivation occurs in the rear and lower regions of the brain." '737 Patent, 77:28-48; see also '490 Patent, 82:35-55 (similar).

- 181. According to the '737 Patent specification (and similarly the '490 Patent specification), areas of deactivation of the active NEST device compared to SHAM were observed. Deactivation was observed to occur in the rear and lower regions of the brain. In this context, deactivation refers to decreased blood flow compared to SHAM because activation refers to increased blood flow compared to SHAM. For example, the passage above states that "[a] significant portion of the cortex was shown to have increased blood flow for the active subjects (using the NEST device) compared to sham. Much of this activation occurs in the prefrontal cortex." (emphasis added) Therefore, increased blood flow is associated with activation and consequently decreased blood flow is associated with deactivation. Therefore, the specification provides an explicit example of decreased blood flow compared to SHAM (e.g., a control).
- 182. The prosecution history for the '737 Patent provides further support for the claim limitation and that a POSITA would understand the meaning of the claim limitation. The '737 Prosecution History discloses:

"With respect to Claims 1 and 2, as amended, Katz fails to teach or suggest moving

"an intrinsic frequency of a specified EEG band of the subject toward a pre-selected intrinsic frequency of the specified EEG band" and with respect to Claim 1, Katz further fails to teach or suggest moving "a Q-factor of an intrinsic frequency within a specified EEG band of a subject toward a preselected O-factor." Additionally, Katz fails to disclose or suggest that "the pre-selected intrinsic frequency is a frequency that increases blood flow in the cortex of the subject" or that "the preselected O-factor is a Q-factor that increases blood flow in the cortex of the subject" as required in Claim 1. Similarly, with respect to Claim 2, Katz fails to disclose or suggest that "the pre-selected intrinsic frequency is a frequency that decreases blood flow in a lower region of the brain of the subject."" '737 Prosecution History at *1308 (February 13, 2014 Amendment in Response to Non-Final Office Action, p. 6). (emphasis in original).

- 183. In the foregoing, the prosecution history states that Katz fails to disclose or suggest that "the pre-selected intrinsic frequency is a frequency that decreases blood flow in a lower region of the brain of the subject." Id. The Examiner understood the meaning of this phrase as evidenced by the allowance of the application in direct reliance on the amendment made to the claim and the associated argument in support thereof presented above.
- Claim 2 of the '737 Patent recites in part: "wherein the pre-selected intrinsic frequency is a frequency that decreases blood flow in a lower region of the brain of the subject." This claim limitation can be compared to Claim 1 of the '737 Patent which recites in part: "wherein the pre-selected intrinsic frequency is a frequency that increases blood flow in the cortex of the subject...." I have been informed that claim terms should be interpreted consistently and not in a manner which renders one superfluous or conflicting with another. Because claims should be interpreted consistently, Claim 1 of the '737 Patent informs Claim 2 of the '737 Patent. That is, the cortex of the subject does not have a decrease in blood flow for a pre-selected intrinsic frequency because this would be counter to Claim 1. Based on this information, it is clear that the lower region of the brain of the subject cannot include the cortex because the blood flow increases in the cortex.
- The specification of the '737 Patent further supports this interpretation. The '737 185. Patent discloses:

A significant portion of the cortex was shown to have increased blood flow for the active subjects (using the NEST device) compared to sham. Much of this

activation occurs in the prefrontal cortex. Using the therapy, activation of the cortex occurs, especially in the frontal region, whereas **deactivation occurs in the rear and lower regions of the brain**. '737 Patent, 77:42-48; *see also* '490 Patent, 82:49-55. (emphasis added).

Therefore, the specification further supports an interpretation that the lower region of the brain refers to subcortical because a significant portion of the cortex has increased blood flow and therefore cannot be deactivated.

186. The Prosecution History of the '737 Patent confirms that a POSITA would understand "lower region of the brain" with reasonable certainty. Claim 2 was originally presented on November 11, 2010 to recite in part: "wherein the pre-selected intrinsic frequency is a frequency that decreases blood flow in a lower region of the brain of the subject." '737 Prosecution History, at *123 (Nov. 11, 2010 Claims). In the first Office Action, the Examiner rejected Claim 7 for lacking antecedent basis but he did not reject Claim 2 as being indefinite. Therefore, the Examiner clearly understood the meaning of "lower region of the brain" because the Examiner had an opportunity to reject Claim 2 for being indefinite but did not reject the claim on such basis.

187. Claim 1 of the '490 Patent recites in part:

- b) a processor configured to control the magnetic field based on said subject data value, wherein the magnetic field is configured to
- i) move the first intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using said magnetic field,
- ii) move the Q-factor of the first intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using the magnetic field,
- iii) move the coherence value by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to the head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value, or
- iv) move the EEG phase of the specified EEG frequency, wherein the magnetic field comprises a first magnetic field that is in-phase with the second magnetic field or a first magnetic field that is out of phase with the second magnetic field; and

wherein the magnetic field increases the blood flow of a cortex of the brain or decreases the blood flow of a lower region of the brain. (emphasis added).

- 188. According to Claim 1 of the '490 Patent, "the magnetic field...decreases the blood flow of a lower region of the brain." The specification provides support for this claim limitation and would allow a POSITA to understand its meaning with reasonable certainty. *See* '490 Patent, 82:35-55 (*supra*).
 - 189. The '490 Patent Prosecution History discloses with respect to this limitation:

Additionally, neither Katz nor Souder disclose or suggest comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject, wherein the magnetic field generator comprises information and a processor that controls the magnetic field and wherein the magnetic field is configured to increase the blood flow of at least a cortex of the brain or **decrease the blood flow of a lower region of the brain**." '490 Prosecution History at *1805 (July 7, 2014 Response to Final Office Action, p. 8). (emphasis added).

- 190. The Prosecution History states that neither Katz nor Souder disclose the limitation. Because the application was allowed, the Examiner was clearly able to understand the meaning of this limitation.
- 191. Therefore, the intrinsic evidence (claims, specification, and prosecution history) confirms that a POSITA would understand "decreases blood flow" ('737 Patent, Claim 2) or "decreases the blood flow" ('490 Patent, Claim 1) with reasonable certainty.
- 192. In light of the intrinsic evidence, a POSITA would also understand "lower region" of the brain with reasonable certainty to mean subcortical, i.e., the part of the brain below the cerebral cortex.
- 193. The intrinsic evidence for the '490 Patent also establishes that "lower region of the brain" had a meaning that a POSITA would understand with reasonable certainty. Claim 1 of the '490 Patent recites: "wherein the magnetic field increases the blood flow of a cortex of the brain or decreases the blood flow of a lower region of the brain." Therefore, the claim explicitly establishes that the magnetic field increases the blood flow of a cortex of the brain and therefore the lower region of the brain cannot include the cortex.
- 194. The Prosecution History of the '490 Patent establishes that a POSITA would understand lower region of the brain with reasonable certainty. Applicant amended Claim 12

(which became Claim 1 of the '490 Patent) to recite in part: "wherein the magnetic field increases the blood flow of cortex of the brain or decreases the blood flow of a lower region of the brain." '490 Prosecution History, at *1526 (Mar. 19, 2014 Amendment/Request for Reconsideration After Non-Final Rejection, p. 3-4). The Examiner rejected Claim 12 for lacking antecedent basis for "a head" but did not reject the claim for being indefinite in relation to "a lower region of the brain." '490 Prosecution History, at *1734 (April 7, 2014 Final Rejection, p. 2). Therefore, the Examiner clearly understood the meaning of "a lower region of the brain" because, if the Examiner did not understand the meaning of "a lower region of the brain," I understand that the Examiner would have rejected that portion of the claim as being indefinite.

- 195. Therefore, the intrinsic evidence for the '490 Patent establishes that a POSITA would understand the phrase "lower region of the brain" with reasonable certainty.
- 196. The extrinsic evidence further establishes that a POSITA would understand the phrase "lower region of the brain" with reasonable certainty. A google scholar search for "lower region" and "brain" limited to the range between 1980 and 2008 returns 2,770 results. Thus, the phrase "lower region of the brain" is a phrase that is used in the field and one that is well understood by a POSITA.
- Furthermore, although not in my opinion necessary, given all of the supporting intrinsic evidence, the extrinsic evidence similarly confirms that a lower region of the brain is subcortical which would include the brainstem, cerebellum, and limbic system, among others. See e.g., Bear, M., Connors, B., & Paradiso, M.A., Neuroscience: exploring the brain, enhanced edition. (2020). The disclosure in this textbook would have been consistent with the state of the art in 2008.

198. Dr. Dempsey asserts that:

significant experimentation would have been required to determine the effect of increasing versus decreasing the intrinsic frequency on blood flow in a cortex or a "lower region of the brain." (This is also because the claimed "lower region of the brain" is not well defined and could mean a host of different possibilities as explained below). Dkt. 34-1, Dempsey Declaration, p. 9.

As discussed *supra* in this Section, specific examples in the specification provide guidance to a POSITA. For example, the specification for the '737 Patent (and similarly the '490 Patent) provides a clinical study in Example 14 that relates intrinsic frequency, HAMD-17 score, and regional cerebral blood flow. A clinical study provides ample guidance to a POSITA who would try to determine the effect on increasing versus decreasing the intrinsic frequency on blood flow in a cortex or a lower region of the brain.

I have been informed by counsel that a degree of experimentation is permissible as long as the degree of experimentation is not undue. I have been informed by counsel that experimentation may be permissible if merely routine or if the specification in question provides a reasonable amount of guidance. Here, the experimentation to determine the effect of increasing versus decreasing the intrinsic frequency on blood flow in a cortex or a lower region of the brain is routine. Furthermore, the specification provides a reasonable amount of guidance for a POSITA to practice the claim as detailed above. A POSITA would understand how to obtain the result described.

Dr. Dempsey also asserts that: 200.

Moreover, in the field of neuroscience, a POSITA would never claim that blood flow in the brain uniformly or binarily increases or decreases.... This is because blood flow in the brain is highly variable and will show significant variation across multiple points in the brain. In the case of measuring blood flow in the brain generally, it is very well possible that blood flow in one section of the lower region of the brain increases, but another decreases. Dkt. 34-1, Dempsey Declaration, p. 10-11. (emphasis added).

Dr. Dempsey has failed to understand that functional magnetic resonance imaging can be used to measure brain activity by detecting changes associated with blood flow. That is, when an area of a brain is in use, blood flows that to area of the brain. Therefore, there are techniques to measure the increase or decrease in blood flow in portions of the brain. Dr. Dempsey's argument that there are no binary increases or decreases in blood flow is wrong.

In addition (as described above in the specification), when a magnetic field is 201. applied to the cortex, blood flow tends to increase in the cortex. When blood flow to the cortex 202. Consequently, it is my opinion that a POSITA would understand the meaning of the phrases and the scope of the claims in which they appear with reasonable certainty. In addition, it is my opinion that a POSITA would understand how to practice the claims.

XIV. "ADJUSTING [A SETTING].../[FREQUENCY]/[OUTPUT]"

203. I understand that the Defendant disagrees with Wave about the proper construction of the phrase "Adjusting [a setting].../[frequency]/[output]" as that phrase appears in Claims 1 and 4 of the '408 Patent and Claims 1 and 2 of the '737 Patent. The Parties' proposed constructions are set forth in the chart below.

Claim Term/Phrase	Plaintiff's Construction	Defendant's Construction
Adjusting [a setting]/[frequency]/[output] '408 Patent, Claims 1, 4	Not indefinite or invalid.	Indefinite & Invalid: Not enabled/lacking written description/failure of best mode.
'737 Patent, Claims 1, 2		

- 204. A POSITA would understand the claim phrase "adjusting [a setting].../[frequency]/[output]" for similar reasons to those provided in Sections XI and XII. That is, a POSITA would understand how to use magnetic field parameters to move the alternative limitations (i.e. intrinsic frequency, Q-factor, coherence value, and EEG phase) to achieve the purpose of the subject claims. In addition, a POSITA would understand how to control the magnetic field to move each of the alternative limitations (e.g., intrinsic frequency, Q-factor, coherence value, and EEG phase) to achieve the purpose of the subject claims.
- 205. As set forth below, the claims, specification, and prosecution history provide a POSITA with the information needed to understand the meaning of "adjusting [a setting].../[frequency]/[output] in the context of the subject claims.
 - 206. For instance, Claim 1 of the '408 Patent recites in part: "
 - (a) adjusting a setting of a magnetic field such that the magnetic field is configured to do one or more of the following:

move an intrinsic frequency of a specified EEG band of the subject toward a target intrinsic frequency of the specified EEG band using the magnetic field, move a Q-factor of the intrinsic frequency toward a target Q-factor of the intrinsic frequency using the magnetic field,

move a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value using the magnetic field wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to the head of the subject; and

move an EEG phase between two sites in the brain of a subject of a specified EEG frequency toward a target EEG phase of the specified EEG frequency using the magnetic field wherein the magnetic field comprises one or more magnetic field generators that are of the same frequency and are in-phase with each other, of the same frequency and out of phase with each other, or a combination thereof...

- 207. A POSITA would therefore understand how to move the alternative limitations (e.g., intrinsic frequency, Q-factor, coherence value, and EEG phase) as set forth in Section XI and a POSITA would understand how to control the magnetic field (as set forth in Section XII). Therefore, a POSITA would understand how to adjust a setting of a magnetic field to move the alternative limitations to achieve the objective of the subject claims.
- 208. Claim 4 of the '408 Patent recites in part: "adjusting frequency of said magnetic field based on the EEG data of the subject; and repeating the applying step with an adjusted frequency." A POSITA would know how to adjust the frequency for the same reasons that the POSITA would understand how to control the magnetic field (as set forth in Section XII).
- 209. Claim 1 of the '737 Patent recites in part: "(a) adjusting output of a magnetic field...." Claim 2 of the '737 Patent similarly recites in part: "(a) adjusting output of a magnetic field...." A POSITA would know how to adjust the output of the magnetic field for the same reasons that the POSITA would understand how to control the magnetic field (as set forth in Section XII).
- Therefore, a POSITA would understand the meaning of claim phrase in Claims 1 210. and 4 of the '408 Patent and Claims 1 and 2 of the '737 Patent, for at least the reasons provided

in Section XI and Section XII.

211. The specifications for the '408 Patent and the '737 Patent further establishes that a POSITA would understand the meaning of the claim phrase with reasonable certainty.

212. 'The '408 Patent discloses:

FIG. 7 shows an exemplary embodiment of the pMERT or NEST device. In this embodiment, a button EEG electrode is located on the concave Surface of the device and a second reference electrode extends via a wire from the side of the device. The display and control buttons are located on top of the device to provide information and allow the user to adjust parameters and enter patient data. A USB port is located at the top rear of the device, to allow it to be connected via a USB cable to a PC, allowing uploading of data and downloading of a dosage quota. '408 Patent 15:24-33; see also '408 Patent, 47:6-48:23.

213. The '408 Patent further discloses:

FIGS. 31 and 32 show the results of a clinical trial utilizing the NEST device and methods for the treatment of depression as provided herein. A device was used such as shown in FIG. 19, with permanent magnets arranged as shown in FIG. 16. In the method used in this trial, a magnetic field was adjusted to influence the Qfactor of an intrinsic frequency of each individual within the alpha-band. The magnetic field was applied close to the head of the subject. EEG readings were taken before treatment began. A Cadwell Easy 2.1 EEG system was used to take a 19-lead EEG reading. The intrinsic frequency in the alpha band (7-11 Hz) was determined using the initial EEG reading. Patients were placed in one of three groups: constant frequency, random frequency, or sham, with equal probability for each group. Patients received treatment every weekday for 30 days. EEG readings were taken after treatment at least on a weekly basis. If the patient was in the "constant frequency" group, the NEST was set to rotate the magnets at the intrinsic frequency. If the patient was in the "random frequency" group, the NEST was set to rotate the magnets at random frequencies between 6 Hz, and 12 Hz, changing frequencies once per second. If the patient was in the "SHAM" group, the magnets in the NEST were replaced with Steel cylinders, thereby imparting no magnetic field to a head of the patient. The patients in this group were divided into two Subgroups with equal probability, with one group having the cylinders rotated at the intrinsic frequency and the other group having the cylinders rotated at random frequencies as noted above. For this clinical trial sixteen (16) subjects received treatment with the NEST device. Eleven (11) subjects responded to treatment (i.e. the Responders) and five (5) Subjects did not respond to treatment (i.e. Non-Responders). Eleven (11) patients received treatment with the SHAM device. '408 Patent 61:47-62:12

214. The '737 Patent further establishes that a POSITA would understand the meaning of the claim phrase with reasonable certainty. The '737 Patent discloses:

In some embodiments of at least one aspect described above, the methods or devices use a Transcranial Magnetic Stimulation (TMS) device. Provided herein is a method comprising adjusting an output current of an electric alternating current source for influencing an intrinsic frequency of an EEG band of a subject toward a target frequency of the EEG band; and applying said output current across a head of the Subject. In some embodiments, the step of adjusting the output current comprises setting the output current to a frequency that is lower than the intrinsic frequency of the subject. In some embodiments, the step of adjusting the output current comprises setting the output current to a frequency that is higher than the intrinsic frequency of the Subject. In some embodiments, the step of adjusting the output current comprises setting the output current to the target frequency. Provided herein is a method comprising determining the intrinsic frequency of the EEG band of the subject; and comparing the intrinsic frequency to the target frequency of the EEG band, wherein the target frequency is an average intrinsic frequency of the EEG band of a healthy population of people, wherein if the intrinsic frequency is higher than the target frequency, the step of adjusting the output current comprises setting the output current to a frequency that is lower than the intrinsic frequency of the Subject, and if the intrinsic.: '737 Patent 14:42-15:20;

215. The '737 Patent further discloses:

FIG. 7 shows an exemplary embodiment of the pMERT or NEST device. In this embodiment, a button EEG electrode is located on the concave surface of the device and a second reference electrode extends via a wire from the side of the device. The display and control buttons are located on top of the device to provide information and allow the user to adjust parameters and enter patient data. A USB port is located at the top rear of the device, to allow it to be connected via a USB cable to a PC, allowing uploading of data and downloading of a dosage quota. '737 Patent 20:4-14; see also '737 Patent, 59:25-60:44.

It is my opinion that based upon the detailed nature of the disclosures contained within the subject patents that a POSITA would understand the meaning of the phrase and the scope of the respective claims, in which it appears, with reasonable certainty. In addition, it is my opinion that a POSITA would understand how to practice the claim.

"ONE SYNCHRONIZED MAGNETIC FIELD" XV.

I understand that the Defendant disagrees with Wave about the proper construction of the phrase "One synchronized magnetic field" as that phrase appears in Claims 1 and 12 of the '408 Patent. The Parties' proposed constructions are set forth in the chart below.

Claim Term/Phrase	Plaintiff's Construction	Defendant's Construction
		Detenuant 5 Constituction

One synchronized magnetic field '408 Patent, Claims 1, 12	Not indefinite or invalid.	Indefinite & Invalid: Not enabled/lacking written description.
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218. It is my opinion that a POSITA would understand the meaning of "one synchronized magnetic field" in the context of the claims, the specification, and the prosecution history. Claim 1 of the '408 Patent recites in part:

move a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value using the magnetic field wherein if the coherence value is higher than the target coherence value, **applying at least two asynchronous magnetic fields** close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, **applying at least one synchronized magnetic field** close to the head of the subject... (emphasis added).

- 219. Claim 12 of the '408 Patent recites in part:
- (c) a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band using the magnetic field wherein if the coherence value is higher than a pre-selected coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the pre-selected coherence value, applying at least one synchronized magnetic field close to the head of the subject...
- 220. A POSITA would understand that the "one synchronized magnetic field" is properly modified by the words "at least." Specifically, by modifying "one synchronized magnetic field," the words "at least" indicate that there can be multiple synchronized magnetic fields. Because there can be multiple synchronized magnetic fields, the meaning of the term "at least one synchronized magnetic field" would be clear to a POSITA.
- 221. Furthermore, the use of "at least one synchronized magnetic field" is in relation to "at least two asynchronous magnetic fields." When this relation is properly considered by a POSITA, it is clear that there should be at least two asynchronous magnetic fields because a magnetic field cannot be asynchronous with itself. However, a POSITA would also understand that a single magnetic field will necessarily be synchronous with itself because the magnetic field

cannot be asynchronous with itself.

222. The specification of the '408 Patent supports the usage of at least one synchronized magnetic field. The '408 Patent discloses:

Provided herein is a method of improving coherence of intrinsic frequencies within a specified EEG band among multiple locations of a brain of a subject, comprising determining the coherence value of the intrinsic frequencies among multiple locations throughout a scalp of the subject; comparing the coherence value from step (a) to an average coherence value of a control group; if the coherence value from step (a) is higher than the average coherence value of the control group, lowering the coherence value of the subject by applying at least two asynchronous magnetic fields close to a head of the subject; if the coherence value from step (a) is lower than the average coherence value of the control group, raising the coherence value of the subject by applying at least one synchronized magnetic field close to a head of the subject. In some embodiments, a NEST device, such as one of the NEST devices (pMERT devices) described herein is used to create the magnetic field of the method. '408 Patent 41:35-51. (emphasis added).

223. The Prosecution History for the '408 Patent further supports this interpretation of "one synchronized magnetic field" in relation to "at least."

Katz fails to disclose or suggest this method, or a device adapted to achieve this. First, Katz fails to disclose or suggest providing a pre-selected coherence value. Second, Katz also fails to disclose or suggest determining a coherence value of the intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band. Third, Katz fails to disclose or suggest adjusting output of a magnetic field to a setting that is operable to .. .influence a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to a head of the subject. Rather, Katz expresses a goal of achieving symmetry in magnitude of the EEG readings starting with asynchronous magnetic fields (0.5Hz, 5 Hz). (See, Column 8 line 39-60, at least). Thus, any secondary preference toward coherent waves appears to use asynchronous magnetic fields to achieve coherent waves. (See, Column 8 line 39-60, at least). This is different with respect to how fields are used in Claim 1 to influence coherence toward the pre-selected coherence value. '408 Prosecution History at *739. (emphasis added).

224. Therefore, a POSITA would understand the meaning of "one synchronized

magnetic field" with reasonable certainty in light of the claims, specification, and prosecution history.

225. Dr. Dempsey argues that the use of the term "synchronized" is entirely unclear and asserts: "[t]he claim term "one synchronized magnetic field" does not make logical sense given that only two or more magnetic fields can be synchronized." Dkt. 34-1, Dempsey Declaration, p. 11. Dr. Dempsey's argument conveniently fails to include "at least" in conjunction with "one synchronized magnetic field." When at least is added to "one synchronized magnetic field" it is clear to a POSITA that "at least one synchronized magnetic field" refers to: (i) a magnetic field, or (ii) multiple magnetic fields that are synchronized. Therefore, Dr. Dempsey's argument is unsupported and, in my opinion, it is clear that a POSITA would understand the phrase with reasonable certainty.

XVI. "CLOSE TO THE HEAD"

226. I understand that the Defendant disagrees with Wave about the proper construction of the phrase "close to the head" as that phrase appears in Claim 1 of the '490 Patent, Claims 1-2 of the '408 Patent, and Claims 1-2 of the '737 Patent. The Parties' proposed constructions are set forth in the chart below.

Claim Term/Phrase	Plaintiff's Construction	Defendant's Construction
Close to the head	Plain and ordinary meaning,	"Near the head, but not on the
Close to the head	namely wherein the head is	head."
'490 Patent, Claim 1	not outside the magnetic field.	
'408 Patent, Claims 1-2	nord.	
'737 Patent, Claims 1-2		

- 227. Dr. Dempsey did not provide any testimony regarding this claim phrase; therefore, I have responded to the arguments made in Defendant's Opening Claim Construction Brief.
- A POSITA would understand the phrase "close to the head" as Wave has proposed. The claims, specification, and prosecution history indicate that the plain and ordinary meaning of "close to the head" is "wherein the head is not outside the magnetic field."

- 229. Claim 1 of the '490 Patent recites in part:
- iii) move the coherence value by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to the head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value... (emphasis added).
- According to the claim, a magnetic field is applied close to the head of the 230. subject. The magnetic field is being applied close to the head for a reason (e.g., in this case to reduce the coherence value or raise the coherence value). The head cannot be outside the magnetic field to achieve such a desired effect.
 - 231. Claim 1 of the '408 Patent recites in part:

move a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value using the magnetic field wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field **close to the head** of the subject;

- (b) applying said magnetic field **close to the head** of the subject. (emphasis added).
- 232. In this claim, the magnetic field is applied close to the head of the subject. As was true in relation to Claim 1 of the '490 Patent, the magnetic field is applied close to the head of the subject to move the coherence value. The head cannot be outside the magnetic field to have such an effect.
 - 233. Claim 2 of the '408 Patent recites in part:

moving at least one of:

an intrinsic frequency of a brain of the subject within a specified EEG band toward a pre-selected intrinsic frequency within the same specified EEG band and a Q-factor of the intrinsic frequency toward a target Q-factor of the intrinsic frequency, by applying a magnetic field **close to a head** of the subject, wherein the magnetic field comprises at least one of(a) a single target frequency within the specified EEG band; (b) a plurality of frequencies within the specified EEG band... (emphasis added).

- 234. In this claim, a magnetic field is applied close to a head for a reason (e.g., to move an intrinsic frequency or Q-factor). The head cannot be outside of the magnetic field to have such an effect.
 - 235. Claim 1 of the '737 Patent recites in part:
 - (b) applying said magnetic field close to a head of a subject; and
 - (c) moving, using the magnetic field, at least one of an intrinsic frequency of a specified EEG band of the subject toward a preselected intrinsic frequency of the specified EEG band and a Q-factor of an intrinsic frequency within a specified EEG band of the subject toward a pre-selected Q-factor... (emphasis added).
- 236. In this claim, a magnetic field is applied close to the head for a reason (e.g., to move an intrinsic frequency or a Q-factor). The head cannot be outside of the magnetic field to have such an effect.
 - 237. Claim 2 of the '737 Patent recites in part:
 - (b) applying said magnetic field close to a head of a subject; and
 - (c) moving, using the magnetic field, an intrinsic frequency of a specified EEG band of the subject toward a pre-selected intrinsic frequency of the specified EEG band... (emphasis added).
- In this claim, a magnetic field is applied close to the head for a reason (e.g., to 238. move an intrinsic frequency). The head cannot be outside of the magnetic field to have such an effect.
- 239. In my opinion, without interpreting their scope, as a POSITA, the claims for the '490 Patent, '408 Patent, and '737 Patent use the phrase "close to the head" to indicate that the head is not outside of the magnetic field.
- The specification of the '490 Patent (and the '408 Patent) supports this 240. interpretation. The specification discloses:

In some embodiments, the strength of the at least one permanent magnetic is from about 10 Gauss to about 4 Tesla. In some embodiments, the distance between the at least one permanent magnet and the subject is from about 0 inches to about 12 inches, from about 1/32 inches to about 12 inches, from about 1/16 inches to about 5 inches, or from about 1 inch to about 5 inches. As used herein, the term "about" when referring to distance between the at least one permanent magnet and Thus, the specification sets up an opposition between the strength of the magnet (and, thus, the strength of the magnetic field) and the distance from the subject. This opposition has meaning because as the strength of the magnet increases, the distance from the subject can also increase. Similarly, as the strength of the magnet decreases, the distance from the subject should also decrease. A POSITA would understand that the ranges provided in the specification for magnetic strength and distance from the subject are intended to maintain the head of the subject within the magnetic field.

- Importantly, the specification explicitly discloses that "the distance between the at least one permanent magnet and the subject is from about 0 inches to about 12 inches." Therefore, there may be a distance of 0 between the permanent magnet and the subject, which shows that Defendant's construction ("Near the head, but not on the head") is inconsistent with the specification.
- The specifications are full of other references to "close to the head" that further 242. support Wave's construction. See Dkt. 29-1 at *29-36.
- In any case, magnets that are used to create a magnetic field (which may be permanent magnets or electromagnets) are typically encased in a protective sleeve or device. For example, MagVenture devices encase the electromagnet in a plastic case. Accordingly, magnets (whether permanent or electromagnets) are not typically placed directly on the head of a subject. I am unaware of any existing TMS device that does not encase the magnet.
- In summary, it is my opinion that a POSITA would understand the meaning of the 244. phrase as proposed by Wave, namely wherein the head is not outside the magnetic field.

XVII. "'SECOND' AND 'THIRD' INTRINSIC FREQUENCY"

245. I understand that the Defendant disagrees with Wave about the proper construction of the term "Second' and 'Third' intrinsic frequency" as that term appears in Claim 1 of the '490 Patent. The Parties' proposed constructions are set forth in the chart below.

Claim Term/Phrase	Plaintiff's Construction	Defendant's Construction
"Second" and "Third" intrinsic frequency	Plain and ordinary meaning,	"Second intrinsic frequency,
	namely a second intrinsic	(which is not the same as the
	frequency and a third	first)."
'490 Patent, Claim 1	intrinsic frequency, wherein	
	the second and third intrinsic	"Third intrinsic frequency
	frequencies are measured	(which is not the same as the
	from different sites in the	first or second)."
	brain, wherein the first	·
	intrinsic frequency may be	
	measured from the same or a	
	different site of the brain as	
	the second and/or third	
	intrinsic frequencies.	

- Dr. Dempsey did not provide any testimony regarding this claim phrase; 246. therefore, I have responded to the arguments made in Defendant's Opening Claim Construction Brief.
- 247. It is my opinion that a POSITA would understand the term "Second' and 'Third' intrinsic frequency" as Wave has proposed in light of the intrinsic evidence (claims, specification, and prosecution history).
 - 248. Claim 1 of the '490 Patent recites in part:
 - a) a non-transitory computer readable medium containing a subject data value comprising
 - i) a first intrinsic frequency of a brain of the subject within a specified EEG
 - ii) a Q-factor of the first intrinsic frequency,
 - iii) a coherence value of a second intrinsic frequency and a third intrinsic frequency, wherein the second and third intrinsic frequencies are from two different sites in the brain of the subject within the specified EEG band, or iv) an EEG phase between two sites in the brain of the subject of a specified EEG frequency, wherein the two sites are different... (emphasis added).
- The first limitation (i) refers to a first intrinsic frequency, but not a second or a 249. third intrinsic frequency. The third limitation (iii) refers to a second intrinsic frequency and a third intrinsic frequency but not a first intrinsic frequency.
 - 250. The specification of the '490 Patent further supports this interpretation.

Specifically, the '490 Patent discloses:

In some embodiments, the device is operable to at least one of: influence the intrinsic frequency of the brain of a subject within the specified EEG band; influence a O-factor of the intrinsic frequency; influence a coherence of intrinsic frequencies among multiple sites in the brain of a subject within a specified EEG band; and influence an EEG phase between two sites in the brain of a subject of a specified EEG frequency. '490 Patent 5:12-19. See also '490 Patent 15:49-56 (similar); '490 Patent 30:9-16 (similar). (emphasis added).

- 251. The prosecution history for the '490 Patent illustrates when "first intrinsic frequency," "second intrinsic frequency," and "third intrinsic frequency" were added to the claim:
 - 12. (Currently Amended) A system for treating depression in a subject comprising: a magnetic field generator adapted to apply a magnetic field to a head of the subject, wherein the magnetic field generator comprises:
 - a) information comprising
 - i) a first intrinsic frequency of a brain of the subject within a specified EEG band,
 - ii) a Q-factor of the intrinsic frequency,
 - iii) a coherence value of a second intrinsic frequency and a third intrinsic frequency, wherein the second and third intrinsic frequencies are from two different sites in the brain of the subject within the specified EEG band, or
 - iv) an EEG phase between two sites in the brain of the subject of a specified EEG frequency, wherein the two sites are different.... '490 Prosecution History at *1799. (underlining in original)

According to the prosecution history, an "or" is used to separate the different limitations.

252. A POSITA would not assume that the "second intrinsic frequency" has to be different from the "first intrinsic frequency." Although the "first intrinsic frequency" and the "second intrinsic frequency" are different measurements, the values can coincide. Similarly, a POSITA would not assume that the "third intrinsic frequency" has to be a different value from the "first intrinsic frequency." The values can coincide. Because the "second intrinsic frequency" and the "third intrinsic frequency" are present in the same limitation (e.g., iii), the "second intrinsic frequency" and the "third intrinsic frequency" are different measurements, although, once again, the actual values can coincide. That is, nothing in the claim requires that the values must be different. Different measurements can have the same values. The only

difference, that I see as a POSITA is on the locations of the measurements of 2 and 3. Wave's construction reflects this difference.

253. It is my opinion that Defendant failed to understand the important distinction between the "location" of the measurement of the First, Second, and Third intrinsic frequency, and the "value" of each such measurement. As such, it is my opinion that Wave's proposed construction is the proper one to adopt for this claim term.

XVIII. CONCLUSION

254. The opinions in this declaration are based upon the information I have received so far. I understand that Defendant will be submitting a responsive claim construction brief concurrently with Plaintiff's responsive brief, and that the Defendant's responsive brief may be accompanied by a supporting expert declaration. I expect that I will be asked to review Defendants' submissions and to provide rebuttal or supplemental opinions in response to Defendant's brief and declaration(s), as necessary. I also am ready and willing to offer testimony at hearing, deposition, or trial if asked to do so.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 31, 2024.

Marom Bikson, Ph.D.